

# EXHIBIT

## 29

**KING**  
**vs.**  
**PARKER, et al.**

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**DR. MICHAELA ALMGREN**

**February 04, 2022**



**Sandy Andrys, LCR, RPR, RMR**

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1                   IN THE UNITED STATES DISTRICT COURT  
2                   FOR THE MIDDLE DISTRICT OF TENNESSEE  
3                   AT NASHVILLE

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4           TERRY LYNN KING,

5                               Plaintiff,

6           vs.

Case No. 3:18-cv-01234

7           TONY PARKER, et al.,

8                               Defendants.

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13                               Videoconference Deposition of:

14                           DR. MICHAELA ALMGREN

15                           Taken on behalf of the Defendants

16                           February 4, 2022

17                           Commencing at 9:02 a.m.

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S T I P U L A T I O N S

The videoconference deposition of  
DR. MICHAELA ALMGREN, was taken by counsel for the  
Defendants, with all participants appearing at their  
respective locations, on February 4, 2022, for all  
purposes under the Federal Rules of Civil Procedure.

All objections, except as to the form of  
the questions, are reserved to the hearing, and that  
said deposition may be read and used in evidence in  
said cause of action in any trial thereon or any  
proceeding herein.

It is agreed that SANDRA ANDRYS, LCR,  
RPR, RMR, Notary Public and Court Reporter for the  
State of Tennessee, may swear the witness remotely,  
and that the reading and signing of the completed  
deposition by the witness was not mentioned.

\* \* \*

DR. MICHAELA ALMGREN

was called as a witness, and having first been duly sworn, testified as follows:

# EXAMINATION

QUESTIONS BY MR. SUTHERLAND:

Q. Good morning, Dr. Almgren. I'm Scott Sutherland. Ms. Andrys, I am with the Tennessee Attorney General's Office. With me on the call are Senior Assistant Attorney General Rob Mitchell, and Assistant Attorneys General Mallory Schiller and Dean Atyia. And we represent the defendants in this case, former commissioner Tony Parker, and the Riverbend Maximum Security Institution, Warden Tony Mays?

MS. LEONARD: Good morning. My name is Lynne Leonard. I am with the Federal Community Defender Office in Philadelphia, Pennsylvania. My colleagues from the same office that are also on this call are Alex Kursman and Ana Baldridge. And our colleague at Bass, Berry & Sims, Jeremy Gunn is also on the call in Nashville, Tennessee. We represent the plaintiff, Terry King, in this case.

MR. SUTHERLAND: All right. Lynne, how are we going to -- we are going to do the exhibits

1 like we did the last time. Rob is going to share  
2 them, and he'll shoot them to you before we talk  
3 about them, if you want to forward them on to  
4 Dr. Almgren.

5 And with that, Rob, if you shoot  
6 Exhibit 1, the Notice of Deposition, to Lynne.

7 MS. LEONARD: We are good with that.

8 I just wanted to ask you, do you want  
9 objections to be subsumed in form objections, or do  
10 you want to discuss those as they come up?

11 MR. SUTHERLAND: (Nods head).

12 MS. LEONARD: I'll try to keep that brief  
13 then.

14 MR. SUTHERLAND: Thank you.

15 Exhibit 1 will be the notice. Lynne, you  
16 can let me know once you have that.

17 (WHEREUPON, a document was marked as  
18 Exhibit Number 1.)

19 MR. MITCHELL: For the record, I will  
20 send both Lynne and Alex the exhibit.

21 MS. LEONARD: Great. Thank you. That  
22 will be helpful.

23 MR. SUTHERLAND: Lynne, just stop me if I  
24 go too fast. Are you good with me asking about it?

25 MS. LEONARD: Yeah. If you want to get

1 started, I think that's fine. The email hasn't come  
2 through yet.

3 Dr. Almgren, I can forward those to you  
4 as soon as I get it.

5 THE WITNESS: That's fine.

6 MS. LEONARD: If you need to take a break  
7 if you are distracted by your email coming in, just  
8 feel free to say something.

9 THE WITNESS: I don't have my email open.  
10 Do I need to open my email, is that something  
11 relevant that I need to have opened up right away, or  
12 is this something that we will talk about; what's  
13 your --

14 MS. LEONARD: Yeah. If you could open  
15 your email and then just look out for emails from  
16 either me or Alex, if we send you these documents  
17 that are going to be sent to us from the Tennessee  
18 AG's office.

19 That's, unfortunately, I think the best  
20 way we could do it, given the Zoom format of this  
21 deposition. Normally we would be able to hand you  
22 the documents across the table and you'd be able to  
23 look at them that way, but this is sort of the  
24 stand-in for that typical procedure.

25 THE WITNESS: Okay.

1 BY MR. SUTHERLAND:

2 Q. So, Dr. Almgren, good morning.

3 A. Good morning.

4 Q. My name is Scott Sutherland. As you heard,  
5 I'm a deputy attorney general with the Tennessee  
6 Attorney General's Office, and I represent the  
7 defendants in this case.

8 And on the screen is a Notice of  
9 Deposition that was provided to plaintiff's counsel  
10 for your deposition here today. Do you see that  
11 document on the screen?

12 A. Yes, I see it.

13 Q. Have you seen it before?

14 A. I believe so. It was -- I received the  
15 email, yes.

16 Q. The date of your deposition in that notice is  
17 today's date. It was based on a request that counsel  
18 for Mr. King, Ms. Leonard and Mr. Kursman, provide us  
19 with dates for your availability.

20 Is that your understanding why we are  
21 here today, this particular day?

22 A. Yes.

23 Q. We had to reschedule you due to a  
24 supplemental report that you tendered recently and  
25 switched it to today, the 4th. And so are you here

1 today pursuant to this notice, is that your  
2 understanding?

3 A. Yes.

4 Q. In the case of Terry King versus Tony Parker,  
5 et al.?

6 A. Yes.

7 Q. Do you understand the deposition is scheduled  
8 for seven hours, excluding breaks, as provided by the  
9 Federal Rules of Civil Procedure. Essentially, we  
10 get to ask you questions for seven hours, it could be  
11 longer than that with breaks. Do you understand  
12 that?

13 A. Yes.

14 Q. Do you understand you have been sworn, you  
15 have sworn an oath to tell the truth during your  
16 testimony here today?

17 A. Yes.

18 Q. And are there any circumstances that you are  
19 aware of that would prevent you from being able to be  
20 here for a seven-hour deposition today?

21 A. No.

22 Q. Have you taken any medication or are you  
23 under the influence of any medication or substance  
24 whatsoever that could affect your ability to provide  
25 factually correct and truthful responses to my

1 questions?

2 A. No.

3 Q. Do you have any medical condition that would  
4 prevent you from being able to provide factually  
5 correct and truthful information to my questions?

6 A. No.

7 Q. The case for which you are being deposed here  
8 is, again, Terry King versus Tony Parker, et al.,  
9 pending in the Middle District of Tennessee.

10 Do you understand you are answering  
11 questions here today related to the King case?

12 A. Yes.

13 Q. What is your understanding of what the King  
14 case is about?

15 A. From what I understand as an expert witness,  
16 so I can only speak on the level that I was involved  
17 in, we will be discussing today what I saw were  
18 the -- are some of the issues that came up with the  
19 preparation of the lethal injection chemicals and  
20 their storage.

21 Q. Okay. Do you understand what the lawsuit by  
22 Mr. King -- what the allegations are?

23 Have you been provided -- have you read  
24 anything that's been filed in the case particularly  
25 to inform you as to what the allegations are in the

1 case?

2 A. Can you explain that further? Do you mean --

3 Q. So this lawsuit has been filed by Mr. King,  
4 do you understand that?

5 A. Yes.

6 Q. Do you understand what the allegations of the  
7 lawsuit are specifically?

8 A. I'm not sure of all of the details.

9 Q. Okay. Have you reviewed the complaint that  
10 was filed or the amended complaint that has been  
11 filed in the case?

12 A. Not right off the bat. I did not read all of  
13 the details.

14 Q. Have you seen the Complaint that's been  
15 filed?

16 A. I guess -- I'll be honest with you. This is  
17 not something that I normally do for a living, so I'm  
18 not familiar with all of the legal terminology. And  
19 so when you talk about allegations and this, I really  
20 don't know what you mean by that.

21 I read the documentation that was  
22 provided by counsel, and I analyzed the data and, you  
23 know, all of the records that were given to me. I'm  
24 not really sure, when you refer to allegations, what  
25 documents are we talking about.

1 Q. Okay. So were you provided a copy of the  
2 amended complaint that was filed by Mr. King in the  
3 lawsuit that sets forth the allegations that he is  
4 making in the lawsuit?

5 A. I honestly don't know.

6 Q. Okay. Have you read anything that's been  
7 filed in the case, any documents that have actually  
8 been filed in the lawsuit?

9 A. Such as?

10 Q. Any of the filings by Mr. King, any of the  
11 responses that have been filed by the State of  
12 Tennessee?

13 A. I don't think so. I read depositions from a  
14 variety of witnesses, records that were provided to  
15 me for review.

16 Q. Okay. I'll talk about that in just a minute.  
17 So you are here as an expert witness on  
18 behalf of the plaintiff, Terry King; is that correct?

19 A. Yes.

20 MR. SUTHERLAND: I'm going to go ahead  
21 and admit Exhibit 1, which is the Notice of  
22 Deposition, as the first exhibit to Dr. Almgren's  
23 deposition.

24 And ask, Rob, if you would put up what's  
25 going to be marked as Exhibit 2, which is -- and

1 Exhibit 3, which is Dr. Almgren's November 17, 2021  
2 report and her supplemental report. I'll start with  
3 the initial report.

4 (WHEREUPON, documents were marked as  
5 Exhibit Numbers 2 and 3.)

6 BY MR. SUTHERLAND:

7 Q. I'm going to -- Dr. Almgren, do you see the  
8 document on the screen that's labeled Expert Report  
9 of Dr. Michaela Almgren?

10 A. Yes.

11 Q. And at the bottom of it, it's got your  
12 signature and dated November 17th?

13 A. That's correct.

14 MR. SUTHERLAND: And, then, Rob, if you'd  
15 scroll down, I think it's her CV following that.

16 BY MR. SUTHERLAND:

17 Q. Does this appear to be the initial report  
18 that you provided plaintiff's counsel in this case?

19 A. Yes, it does.

20 MS. LEONARD: Can I just interject for  
21 one second?

22 Dr. Almgren, I did forward you that email  
23 a couple minutes ago that has the full copy,  
24 full-length exhibits from Mr. Mitchell.

25 THE WITNESS: Yes.

1 MS. LEONARD: They are making that an  
2 exhibit. If you want to open that and look at the  
3 full-length exhibits and make sure that that is your  
4 report, make sure it's your CV and that you are happy  
5 with it.

6 MR. SUTHERLAND: Perfect, that will be  
7 good.

8 THE WITNESS: Okay.

9 BY MR. SUTHERLAND:

10 Q. Will you let us know when you have received  
11 it and have reviewed it, Dr. Almgren?

12 A. I have received it. I'm going to review it  
13 right now.

14 MS. LEONARD: Thank you.

15 THE WITNESS: Okay.

16 BY MR. SUTHERLAND:

17 Q. Does that appear to be a true and correct  
18 copy of your report, your initial report?

19 A. Yes.

20 Q. Okay. Dr. Almgren, you understand the court  
21 reporter is recording the questions that I'm asking  
22 you and your answers today?

23 A. (Witness nodded.)

24 Q. And because of that, and we are on video, you  
25 will need to answer my questions verbally so that she

1 can record your answer. And, of course, that goes  
2 for me, too.

3 Feel free to use hand gestures or  
4 whatever, but just make sure, if you shake your head,  
5 make sure you also shake it and give an affirmative  
6 or a negative answer so that she can record your  
7 answer.

8 A. Absolutely.

9 Q. Okay. I will ask you to allow me to state my  
10 entire question before you give an answer. And I  
11 will try to do the same for you so that we are not  
12 talking over each other, so that she gets my question  
13 and your answer and they are not all jumbled up,  
14 fair?

15 A. Sounds good.

16 Q. If you need to take a break during the  
17 deposition, all you need to do is ask. The only  
18 caveat to that is, if we are in the middle of a  
19 question, you will need to answer the question before  
20 we go off the record.

21 A. Okay.

22 Q. And is there anyone in the room with you  
23 today where you are?

24 A. Unless you count the dog, it's only me.

25 Q. We'll note the dog's presence.

1 Are you at home?

2 A. Yes.

3 Q. Okay. And so if anyone enters the room  
4 during your deposition, I ask that you let me know,  
5 identify the person and the reason they have entered  
6 the room, if you know. Hopefully, you will know.

7 Also, if anyone associated with this case  
8 contacts you by any means during the course of the  
9 deposition, please notify me so that we can put it on  
10 the record. Do you understand that?

11 A. Yes.

12 Q. You shouldn't be discussing your testimony  
13 with anybody associated with this case while I'm  
14 asking you questions; do you understand that?

15 A. Yes.

16 Q. In other words, you can't ask questions and I  
17 can't -- and they can't ask you questions while you  
18 are under oath answering questions for this  
19 deposition; do you understand that?

20 A. Yes.

21 Q. Okay. Other than your computer, do you have  
22 anything else in the room with you, other than your  
23 dog?

24 A. Well, my bottle of water, my daily planner,  
25 it's my office.

1 Q. Any notes related to this case, papers?

2 A. No.

3 Q. Notes of any kind? Okay.

4 I will tell you, as a lawyer practicing  
5 in the case, as in all cases like this, my job here  
6 is to endeavor to learn about areas in which I don't  
7 have any formal education, so that I can and we can  
8 as parties fairly and accurately present that  
9 information to the court in this case. Does that  
10 make sense?

11 Suffice it to say, I'm here to learn  
12 about your knowledge and your opinions on the issues  
13 you have discussed in your report and about which you  
14 plan to testify in this case.

15 You are the person with the specialized  
16 knowledge here; I am certainly not. And the purpose  
17 of me asking questions is for me to understand. I  
18 mean, at the end of the day, hopefully, I'll  
19 understand where you are coming from in terms of your  
20 opinions and the facts and scientific principles that  
21 you believe support those opinions.

22 I always hope to leave a deposition  
23 knowing more than when I started, so if I can  
24 accomplish that today, I will have accomplished what  
25 we set out to do here.

1                   That being said, if you don't understand  
2 my question, please ask me to repeat it or restate  
3 it. Sometimes lawyers ask questions -- may not ask  
4 the questions the way you as a, for example,  
5 pharmacist may. And so if it's more appropriate to  
6 phrase something differently or I can rephrase it in  
7 a way that we both understand, please don't hesitate  
8 to let me know that.

9           A.        Okay.

10          Q.        The goal here is to sort of -- I always hate  
11 to use the word "dumb it down," so I won't  
12 necessarily say dumb it down, but I want to be able  
13 to -- for you to be able to give your answers in a  
14 way that a layperson, certainly a lawyer and judge  
15 can understand these particular facts. Do you  
16 understand that?

17        A.        Yes.

18          Q.        I want to talk to you about deposition  
19 preparation, your preparation for today, ask you some  
20 specific questions about your preparation. Is that  
21 okay?

22        A.        Sure.

23          Q.        Would you think about and explain to me what  
24 all you have done to prepare for your deposition  
25 testimony today?

1 A. So I have looked over my testimony just to  
2 kind of remind myself of what all I discussed. And  
3 so I looked at the electronic copies that you emailed  
4 me, as well of those testimonies, and I looked over  
5 those.

6 Q. When you say "testimonies," what do you mean  
7 by that?

8 A. I guess, again, my legal terminology perhaps  
9 isn't the most appropriate, considering I am not a  
10 lawyer.

11 Q. No, that's okay.

12 A. Because I'm the expert, my expert analysis or  
13 expert reports is what I looked at.

14 Q. All right. So before today, you reviewed  
15 your report?

16 A. Yes. I reviewed both reports prior, and I  
17 looked at the USP guidelines, specifically at the  
18 quality requirements for midazolam, just to  
19 double-check that I have -- not double-check, but  
20 just to remind myself of what were some of the  
21 requirements.

22 Q. And when you say you looked over the quality  
23 requirements for midazolam, what specifically -- what  
24 specific provisions are you talking about?

25 A. So those are the actual monographs. There is

1 a monograph for midazolam and there is a monograph  
2 for midazolam injection, and so I wanted to look at  
3 both.

4 Q. And where are they located within the USP?

5 A. These are part of the USP. I have electronic  
6 access, and so I just search "midazolam." And it's a  
7 chapter, it's a monograph.

8 Q. So it's a specific chapter within USP?

9 A. So it's a specific monograph. When you look  
10 at the USP guidance, you have the book that has  
11 initial all the chapters and you have general  
12 chapters of methodology, and that's followed by  
13 monographs.

14 Q. I understand. What's a monograph?

15 A. It is basically kind of like a summary in  
16 this case specific to, for example, midazolam. A  
17 monograph will contain all of the quality  
18 requirements for the midazolam, what you need to test  
19 in order to show that is in compliance with USP  
20 requirements.

21 Q. So is it -- all right. So let me back up and  
22 ask you.

23 Can you just define generally what a  
24 monograph is?

25 A. As in what a monograph --

1 Q. What is a monograph?

2 A. It is a set of guidelines, I guess, set of  
3 information, certain information that is provided.

4 Q. Okay. And is a monograph sort of -- is it  
5 always the same? I mean, not -- obviously, for  
6 different drugs it would be different.

7 But does it contain the same information,  
8 each monograph, related to the specific drug  
9 involved?

10 A. So --

11 Q. I'm trying to get an idea of what generally  
12 is a monograph.

13 A. So, basically, like I said, in the case of  
14 USP, it provides you with guidance on quality  
15 standards. What are the requirements for each drug  
16 that the drug needs to meet in order to be USP  
17 compliant.

18 So if you are going to say that midazolam  
19 is USP compliant, you need to perform all of the  
20 testing that is listed in the USP monograph.

21 The monograph, as you stated, will vary  
22 between drugs, because different medications will  
23 have different quality requirements.

24 Q. Okay. Does it also -- so does this have to  
25 do with compounding midazolam?

1 A. It does, because when you are preparing a  
2 compounded midazolam, you are basically making a  
3 midazolam injection. And so there is a monograph  
4 that's for midazolam injection that is different from  
5 midazolam raw material, which is an API or active  
6 pharmaceutical ingredient.

7 Q. Does the -- so the monograph itself simply  
8 says all of the things that you -- provides all of  
9 the guidelines for what you need to do in order to  
10 guarantee that the compounded midazolam is USP  
11 compliant?

12 A. So those would be two separate monographs.  
13 So if you were to look at the API, meaning active  
14 pharmaceutical ingredient, if you purchase dry  
15 powder, you are going to test it according to  
16 midazolam monograph, and that's just for the raw  
17 material itself.

18 If you are going to compound an  
19 injectable midazolam, you are going to pull up  
20 monograph for midazolam injection.

21 Q. And that's what you did?

22 A. I looked at both. I looked at midazolam API  
23 and midazolam injection.

24 Q. Do you happen to know specifically where  
25 those monographs are located, like what page numbers?

1 A. These are not in a -- I don't have a printed  
2 copy. USP is available -- the compendium is  
3 available. Every year they publish it. But most of  
4 the places nowadays you will not buy the book because  
5 it comes with quarterly updates.

6 Q. Right.

7 A. So what you do is you purchase the  
8 subscription. And so they don't really have page  
9 numbers that I'm aware of, you would just search the  
10 compendium.

11 Q. You would search the -- search the  
12 compendium. What did you -- tell me how you put it  
13 in there so that I would know how to --

14 A. So there's a search bar at the top, it's  
15 basically a screen where you pull up a USP. You will  
16 see this, you know, main page. And on there, there  
17 will be -- you know, there's a search bar in the top.  
18 There's some disclaimers at the bottom.

19 They typically will show you on that main  
20 page what is the upcoming changes. They will give  
21 you kind of a heads-up, so if you have any changes  
22 you need to make in any of your current standards or  
23 current procedures, you can do that.

24 And so at the top is a search bar, and  
25 you type in "midazolam" or "midazolam injection,"

1 and --

2 Q. Is that what you did?

3 A. Yes.

4 Q. So what did you type in first?

5 A. So first I typed in midazolam.

6 Q. Okay. So if I were to look at the USP  
7 compendium online and I went to the search bar and I  
8 type in midazolam, did you put in midazolam monograph  
9 or will that just -- is that all you put in, was  
10 midazolam?

11 A. Just midazolam. It will automatically  
12 recognize that you are searching for a drug.

13 Q. Okay. And if I type in midazolam and hit  
14 search, what's going to come up?

15 A. The page that basically is showing the  
16 midazolam electronic monograph, it's showing all of  
17 the quality requirements.

18 Q. Is that for the API or the injection?

19 A. So if you search just midazolam, it will be  
20 API.

21 Q. And you did that?

22 A. Yes.

23 Q. And when did you do that?

24 A. I did that this morning.

25 Q. Okay. So you typed in midazolam and you hit

1 search and it brought up the API monograph?

2 A. Yes.

3 Q. All right. And then did you also do a  
4 different search?

5 A. So I looked at that. And then I said, let me  
6 look at the midazolam injection to review that, those  
7 standards as well.

8 Q. And so what did you search to get that, or is  
9 it in the same --

10 A. No. I typed in "midazolam injection."

11 Q. Okay.

12 (An off-the-record discussion was held.)

13 MR. SUTHERLAND: I'll do better and,  
14 Dr. Almgren, we'll just do better together. You can  
15 just wait until I stop talking, and I'll try to -- or  
16 I will not talk while you are talking.

17 THE WITNESS: It might be I have a little  
18 delay with my Internet, it could easily be, because I  
19 feel like I do give you the time, but I wonder if  
20 there is some kind of a -- I don't know. I think  
21 there's a delay in the Internet.

22 MR. SUTHERLAND: I think that's fair.

23 BY MR. SUTHERLAND:

24 Q. So we were talking about things you reviewed  
25 to prepare for your deposition, and one of the things

1 you looked at was the USP guidelines for quality  
2 requirements for midazolam, the midazolam monographs,  
3 which you looked at this morning, and you have  
4 indicated, as I understand it, that you went into the  
5 USP website in the search bar and typed in midazolam  
6 and reviewed the midazolam API monograph, and then  
7 you went back to the search and searched midazolam  
8 injection and reviewed the injectable midazolam  
9 monograph; is that correct?

10 A. That's correct.

11 Q. And if I do the same thing, then I should  
12 be -- then I will be able to see what you reviewed  
13 today, fair?

14 A. Yes.

15 Q. Okay. What else did you review to prepare  
16 for your deposition today?

17 A. As I stated, I did look over both of my  
18 testimonies briefly, and I believe that's it. I  
19 don't think I reviewed any additional documents --  
20 no, no, one more thing.

21 I did review -- I went back to the lethal  
22 injection protocol from the Riverbend facility, the  
23 electronic copy, and I specifically looked at pages  
24 35 through 40 to review the handling of the drugs,  
25 but just really briefly.

1 I didn't really spend a lot of time, I  
2 just wanted to really familiarize myself with the  
3 procedure should the questions come up.

4 MR. SUTHERLAND: Rob, why don't you go  
5 ahead -- I'm going to -- strike that.

6 BY MR. SUTHERLAND:

7 Q. Dr. Almgren, when you reviewed the --

8 MR. SUTHERLAND: Rob, did you send 2 and  
9 3?

10 MR. MITCHELL: I did.

11 MR. SUTHERLAND: Okay.

12 BY MR. SUTHERLAND:

13 Q. So, Dr. Almgren, when you received the email,  
14 did the email contain both your initial report and  
15 your supplemental report?

16 A. Yes.

17 MR. SUTHERLAND: I'm going to move to  
18 make exhibits -- Dr. Almgren's November 17, 2021  
19 report and the supplemental report Exhibits 2 and 3  
20 to this deposition.

21 Rob, if you could forward the Exhibit 4,  
22 which is going to be a copy of the protocol, to  
23 Lynne. And then I'm going to ask you -- Lynne will  
24 forward you the protocol and we can talk about that  
25 for just a minute.

1 THE WITNESS: Okay.

2 MR. SUTHERLAND: Rob, if you could share  
3 that when you have a chance.

4 (WHEREUPON, a document was marked as  
5 Exhibit Number 4.)

6 MR. SUTHERLAND: Dr. Almgren, if you  
7 would let me know when you receive that.

8 THE WITNESS: I see it on the screen, but  
9 I haven't received it in the email yet.

10 MS. LEONARD: I don't have it either, but  
11 as soon as it comes to me, I will forward it on to  
12 Dr. Almgren.

13 MR. SUTHERLAND: Do you want me to wait,  
14 Lynne?

15 MS. LEONARD: No, I think if you want to  
16 get started, and if we run into a situation where we  
17 need to see it, maybe we could just sort of take a  
18 pause.

19 MR. SUTHERLAND: Yeah.

20 MS. LEONARD: It just came through, so  
21 I'm going to forward it to you right now,  
22 Dr. Almgren.

23 THE WITNESS: Thank you.

24 BY MR. SUTHERLAND:

25 Q. Dr. Almgren, I'm going to show you, you can

1 see it on the screen, the Lethal Injection Execution  
2 Manual, Execution Procedures for Lethal Injection.

3 Does that look like the document you were  
4 just talking about?

5 A. Yes.

6 Q. That you reviewed this morning?

7 A. Yes.

8 Q. Okay. At the bottom left-hand corner of that  
9 document --

10 MR. SUTHERLAND: Rob, if you could scroll  
11 down to the bottom.

12 BY MR. SUTHERLAND:

13 Q. It says, revised July 5th, 2018. Is that the  
14 version that you reviewed, Dr. Almgren?

15 A. I am not 100 percent sure. I would have to  
16 go back and look in my electronic copy, because I do  
17 not -- I'm not sure of that particular revision note.

18 Q. Okay. You indicated that you read certain  
19 pages in preparation for your deposition, pages 35  
20 through 40.

21 Have you previously reviewed this entire  
22 document?

23 A. I have.

24 Q. From start to finish?

25 A. It was a long time ago, so I did not do that

1 in preparation for this deposition, but I have done  
2 this probably whenever I started on this case,  
3 whenever last --

4 Q. Is it fair to say that you have read every  
5 word of the protocol?

6 A. No, I don't know that that's fair to say,  
7 because I really focused on the pages that are truly  
8 relevant to me.

9 The document is what, 99 pages long. So,  
10 no, the pages that were not relevant, I probably  
11 skimmed through to get an understanding of what goes  
12 on, but I don't think that I could, you know,  
13 summarize exactly what all is contained in this  
14 document, because like I said, I really -- I was not  
15 hired to analyze the entire protocol. I was really  
16 focused on the handling of the medications.

17 MR. SUTHERLAND: Rob, could you go to  
18 page 35.

19 BY MR. SUTHERLAND:

20 Q. All right. Dr. Almgren, this is page 35.  
21 Does that look like the first page that you reviewed  
22 in preparation for today?

23 A. I believe so. Can you scroll above, let me  
24 see what is on page 34?

25 MS. LEONARD: Dr. Almgren, if you want to

1 check your email and see if the full document came to  
2 you, just so you have it handy and can do some  
3 scrolling.

4 THE WITNESS: Let me check. Nothing yet.  
5 I did look at this. I did see this page. So I guess  
6 35 or 34 was -- I guess I looked at this page as  
7 well. But this really is just a summary, so I really  
8 focused on 35 and so forth.

9 MR. SUTHERLAND: Could you scroll down to  
10 35 -- could you scroll to 35.

11 BY MR. SUTHERLAND:

12 Q. So you reviewed this page today, or in  
13 preparation for the deposition?

14 A. Yes.

15 Q. And then 36?

16 A. Yes.

17 Q. Did you read that page?

18 Okay. 37?

19 A. Yes.

20 Q. And that deals with commercially manufactured  
21 drugs; is that correct?

22 A. Yes.

23 Q. All right. And then 38?

24 A. Yes.

25 Q. 39?

1 A. Yes.

2 Q. 40?

3 A. Yes.

4 Q. Is that it?

5 A. That's it. I was really focused primarily on  
6 the handling of the drugs. For my expert analysis, I  
7 did review more than just the pages that I just  
8 mentioned. This is just -- particularly the five  
9 pages I looked at were strictly in preparation for  
10 this morning.

11 Q. I understand.

12 What other documents did you review in  
13 preparation for your deposition?

14 A. That was it. You mean -- I prepared -- I got  
15 up early this morning and then I reviewed, like I  
16 said, my testimonies, the USP monographs, and this.

17 Q. All right. Before this morning, have you  
18 reviewed -- I guess your report, Exhibit 2, and your  
19 supplemental report indicate that you reviewed a  
20 number of other documents.

21 And while you may not have technically  
22 reviewed them in preparation for the deposition, they  
23 are certainly, I guess, part of your knowledge. And  
24 I want to talk to you a little bit about those, okay?

25 A. Sure.

1 MR. SUTHERLAND: Rob, can you pull up  
2 Exhibit 2, the initial report at page 2.

3 BY MR. SUTHERLAND:

4 Q. Dr. Almgren, at page 2 of your initial report  
5 from November 17, 2021 in Section II, Roman Numeral  
6 II, you say -- you list materials relied upon. Do  
7 you see that?

8 A. Yes.

9 Q. And in numerical paragraph 6 you list a  
10 number of items, and I'd like to ask you some  
11 questions about those.

12 You were provided -- 6-A is a copy of the  
13 protocol, which is what we just went over, right?

14 A. Yes.

15 Q. And then 6-B is depositions of the drug  
16 procurer; the executioner; the pharmacist; Warden  
17 Tony Mays; Associate Warden Ernest Lewis; pharmacy  
18 owner; IV team member 1; IV team member 2; IV team  
19 member 3; Commissioner Tony Parker in both his  
20 individual capacity and as an official designee of  
21 the Tennessee Department of Corrections, which would  
22 be two separate depositions.

23 Are you familiar with that?

24 A. There was a lot of documents that I reviewed.  
25 It has been a while since I have reviewed them, but

1 I'm assuming I listed them -- they were in the  
2 Dropbox. I probably glanced at them, yes.

3 Q. Debbie Inglis, a physician; EMT 1; EMT 2; and  
4 EMT 3.

5 So those documents were provided to you  
6 in the Dropbox?

7 A. Yes.

8 Q. Did you review each of those depositions from  
9 start to finish?

10 A. So, yes, I reviewed them. And depending how  
11 relevant I found them, is how much I paid attention.  
12 There are some that were less relevant to what I was  
13 focused on than others.

14 Q. Did you read each deposition from beginning  
15 to end?

16 A. Yes.

17 Q. All of the ones that are listed here?

18 A. Yes.

19 Q. Laboratory reports for compounded drugs, 6-C.

20 6-D, midazolam storage and preparation  
21 instructions.

22 6-E, potassium chloride preparation  
23 instructions.

24 6-F, handwritten inventory list.

25 And 6-G, prescriptions and sample

1 prescription for lethal injection chemicals.

2 So are there any documents -- and I guess  
3 your supplemental report cites to another production  
4 of information that you reviewed which resulted in  
5 your supplemental report; do you recall that?

6 A. Yes.

7 Q. Other than the documents that I've just gone  
8 over that you have listed here, and the documents  
9 that you refer to in your supplemental report, are  
10 you relying on anything else in forming your  
11 opinions?

12 A. So I provided a list of resources that I had  
13 used, USP Chapter 797 being one. There are a few  
14 other USP chapters that I quote throughout my  
15 testimony that I also have relied upon.

16 There is a document, it's a guidance from  
17 FDA, that tells you about how comparable -- or,  
18 really, not comparable, on how to make decisions  
19 about whether you can use EP, BP, or other  
20 pharmacopeia monographs to make decisions about  
21 purchasing and using your API, so I used that  
22 guidance as well.

23 Those are the things that I can think  
24 right off the bat. But I did supply a list of all of  
25 my references for your review. I supplied it. I

1 uploaded it to the Dropbox for the attorneys that I  
2 work with, and they had supplied this to you.

3 Q. That includes the FDA guidance on EP and BP  
4 purchasing?

5 A. Yes. And that guidance is really just a  
6 link, so you click on it and you get a document.

7 Q. Got it. Did you review any of the expert  
8 reports, other expert reports in this case?

9 A. I reviewed whatever is listed in the Dropbox.

10 Q. Do you recall having reviewed the expert  
11 reports of any other experts in the case?

12 A. I reviewed whatever is in the Dropbox.

13 Q. Okay. I understand that. What I'm asking  
14 you is, do you have a recollection of having reviewed  
15 any report of any other expert in this case that has  
16 provided a report like your report?

17 Do you have any recollection of having  
18 reviewed any other reports?

19 A. I am trying to remember. I do not believe  
20 so. I work on another case, and so I think that  
21 that's where maybe my confusion comes from, but I  
22 believe that that was all.

23 I can look back at the Dropbox and see  
24 what else is in there. I mean, I'm assuming really  
25 the testimonies that you have, those were the main

1 ones. I think there may have been -- like I said,  
2 I'd have to double-check my notes. I do not have  
3 those.

4 Q. I understand. And as you sit here this  
5 morning, do you have any independent recollection in  
6 this case of having reviewed the report of any other  
7 experts?

8 A. I do not remember. I want to say that there  
9 were -- no, those were -- those were all testimonies,  
10 what you have listed.

11 What happened is, I think when we  
12 uploaded the -- when we -- no, that's a different  
13 case. Yeah, no, I believe that that's all that I  
14 have.

15 For some reason I want to say -- let me  
16 look at this document, give me one second. It's the  
17 document that you have emailed. I want to scroll up,  
18 if there was anything else, but I don't think so,  
19 because these were just all depositions that I've  
20 read that I have formed my opinion upon.

21 Yeah. I apologize, there is not a case  
22 that I've been working on.

23 Q. I understand.

24 A. When I think about the documentation I have  
25 reviewed in a more recent one, and because of that I

1 sometimes make, like, a distinction of which one it  
2 is that I'm trying to remember.

3 Q. I understand. Let me repeat my question.

4 As you sit here this morning, do you have  
5 an independent recollection of, in this case, whether  
6 that you have been provided with any other expert  
7 reports, persons who have given expert reports in  
8 this case?

9 A. I'm trying to remember. It would be helpful,  
10 can I look in the Dropbox and see what documents are  
11 in there for me to remind me? I don't remember. I  
12 don't want to say yes or no because I just honestly  
13 don't remember.

14 Q. Yeah. I mean, if you have access to it, that  
15 would be fine; fine with me.

16 Do you have ready access to that,  
17 Dr. Almgren?

18 A. I do.

19 Q. Okay.

20 A. Yeah. I don't see any expert -- I don't see  
21 anything in here. I see the depositions. Let me  
22 just scroll down and make sure there's not any.

23 These are all -- all I see is I have the  
24 folder with the depositions, and then I have the  
25 background packet which includes the protocol that

1       you have shown.

2       Q.       Okay.

3       A.       And I don't see anything relevant there. And  
4       then I have another folder that just shows the lab  
5       reports sample. It's different files, but that's  
6       all. I don't see any expert witness communication  
7       here in my Dropbox.

8       Q.       You don't have any memory of reviewing any in  
9       this case?

10      A.       Like I said, I honestly do not, but it  
11      doesn't mean -- it's that I worked on another case,  
12      and I did have some analysis there.

13      Q.       Okay. In preparation for your deposition,  
14      did you meet with -- have any meetings with anyone?

15      A.       Yes, I did meet with the attorneys on  
16      Wednesday morning.

17      Q.       Just one meeting?

18      A.       For the preparation, yes.

19      Q.       And how long was that meeting?

20      A.       A couple hours.

21      Q.       And who was present for the meeting?

22      A.       I know Lynne was present and Alex Kursman  
23      were present. The others, I don't recall the names.

24      Q.       How many people were there?

25      A.       I would say five or six.

1 Q. Maybe five. Do you know if they were people  
2 that worked in the same office with Mr. Kursman or  
3 Ms. Leonard?

4 A. I am assuming so.

5 Q. Okay. Was it a video, a Zoom meeting?

6 A. Yes.

7 Q. Okay. And you just had that one meeting?

8 A. Yes.

9 Q. How many times have you met with attorneys  
10 for Mr. King all together in the case?

11 A. Via phone or in person?

12 Q. Any meetings.

13 A. I honestly am not sure, a handful of times.

14 Q. More than five?

15 A. No, I don't think so.

16 Q. Was it more than three?

17 A. Probably, maybe three or four; five probably  
18 at the most.

19 Q. Okay. And you say the one on Wednesday  
20 lasted a couple of hours?

21 A. Yes.

22 Q. And do you bill for those meetings?

23 A. Yes.

24 Q. Do you bill for your review of the  
25 depositions?

1 A. Yes.

2 Q. So do you know how many hours you have billed  
3 so far for your services in this case?

4 A. I would have to look.

5 Q. Approximately?

6 A. I would say maybe upwards of maybe 30 or so.

7 Q. Do you know approximately how many hours you  
8 have spent reviewing depositions?

9 A. The majority of that time was spent on that.

10 Q. Okay. So you would say more than 15 hours?

11 A. More than 15 or 50?

12 Q. Well, you said -- 15, I'm sorry. More than  
13 15?

14 A. Oh, yeah, you mean for review of depositions?

15 Q. Yes.

16 A. Yes.

17 Q. Okay. More than 20?

18 A. Probably, yes; I would say so, yes.

19 Q. Twenty-five?

20 A. Very likely, yes; somewhere between 20 and  
21 25, yes.

22 Q. Okay. Other than counsel for Mr. King,  
23 Ms. Leonard, Mr. Kursman, have you discussed any  
24 matters in your report or your testimony about the  
25 case with anyone else?

1 A. Like who?

2 Q. Anyone other than those people.

3 A. No.

4 Q. Other than Ms. Leonard, Mr. Kursman, someone  
5 on the legal team there, have you discussed your  
6 report or your testimony with any other human being?

7 A. My husband. I don't discuss the  
8 technicalities, but I would say, you know, I'm doing  
9 a deposition this morning. And so he's aware that,  
10 you know, I do that.

11 I teach at the university, so I'll say  
12 things like, you know, I work as an expert witness.  
13 We don't discuss specifics of the course -- or the  
14 case or anything, but --

15 Q. I understand.

16 A. -- that level where I just mention that  
17 that's something that I sometimes do.

18 Q. How much time do you think you have spent  
19 total preparing for your deposition today?

20 A. Maybe a couple hours, probably less than --  
21 do you mean including our meeting with the attorneys,  
22 or do you mean --

23 Q. Yes, ma'am.

24 A. -- just my personal?

25 Q. Yes, ma'am.

1 A. I guess a couple hours with the attorneys,  
2 and then maybe I would say another hour or maybe an  
3 hour and a half of separate.

4 Q. I'd like to go through your CV, if we could.

5 A. Okay.

6 MR. SUTHERLAND: Rob, can you put up  
7 Exhibit 2 and scroll down to Dr. Almgren's CV.

8 MS. LEONARD: And, Dr. Almgren, do you  
9 have that, a copy that is available in front of you  
10 from the email?

11 THE WITNESS: Yes. I will open it right  
12 now.

13 MS. LEONARD: Okay, great.

14 MR. SUTHERLAND: Let me know when you are  
15 there, Dr. Almgren, so you will have the ability to  
16 look at it.

17 THE WITNESS: Okay, I'm there.

18 BY MR. SUTHERLAND:

19 Q. What's on the screen, does that appear to be  
20 a true and correct copy of your CV that you provided  
21 to Mr. King's lawyers?

22 A. Yes.

23 Q. Okay. I'd like to go through and spend some  
24 time talking about your CV and I want to start with  
25 your education and employment.

1                   So as I read your CV, you have a bachelor  
2 of science degree in both biology and chemistry, '97,  
3 from Columbia College of South Carolina?

4           A.        Yes.

5           Q.        Not to be confused with the University of  
6 South Carolina?

7           A.        No, separate.

8           Q.        So Columbia College is, I guess, a small  
9 liberal arts school there in Columbia; is that right?

10          A.        Yes, that's correct.

11          Q.        And what did you do after you obtained your  
12 undergrad degree in '97?

13          A.        So I worked for a few years. I'm originally  
14 from Czechoslovakia. So I went back home, I got  
15 married. There were a few things that I did.

16                   Are you asking career wise or are you  
17 asking just the general what --

18          Q.        Yeah, let me back up just a second.

19                   So you got your degree in May of '97; is  
20 that right?

21          A.        Yes.

22          Q.        Your CV shows that you started your first job  
23 in '99.

24          A.        I see.

25          Q.        May of '99?

1 A. Yes.

2 Q. So that's two years?

3 A. Yes.

4 Q. Two years between the time you got your  
5 degree and the time you started your first job?

6 A. Yes. So I worked actually -- looking at  
7 this, I guess I must have put my CV -- I guess when I  
8 was preparing the CV initially, there are a few  
9 irrelevant jobs that I had in between where, you  
10 know, I worked as an intern places. And, like I  
11 said, I got married and I went back home.

12 Q. Let me stop you for just a second.

13 So you got your degree in May of '97.  
14 And if you could walk me from May of '97 until May of  
15 '99, when you started working for GlaxoSmithKline,  
16 that would be helpful?

17 A. Okay. So I worked as a chemist for a  
18 chemical company. I want to say I actually worked,  
19 maybe, there all the way to '99. I was a chemist in  
20 a chemical company.

21 Q. And where was that?

22 A. That was Columbia, South Carolina.

23 Q. What was the name of the company?

24 A. I think it was called Lindau Chemicals. I  
25 think that's what the name was. It was small.

1 Q. How do you spell that?

2 A. L-I-N-D-A-U, Lindau.

3 Q. And what did you do at Lindau?

4 A. I was a chemist.

5 Q. And what were your duties there?

6 A. I worked in a chemistry lab, analyzing  
7 samples.

8 Q. Samples of?

9 A. The chemicals that the company made, raw  
10 materials.

11 Q. Yeah. So what was your job, I guess is what  
12 I'm trying to get at? What were you doing as a  
13 chemist there? I mean, what did the company do?  
14 What did they make, and what was your position with  
15 them?

16 Because you have given lots of detail in  
17 your CV about your jobs with GlaxoSmithKline and with  
18 Pfizer. I'd like to have similar detail about those  
19 other chemistry jobs.

20 A. Okay. Well, with Lindau, I really, you know,  
21 did something along the similar lines. It was  
22 just -- I think one of the reasons it's not listed on  
23 my CV is because it wasn't directly pharmaceutical  
24 related, and so maybe that's why I did not list it;  
25 it was relatively short.

1 But I worked there as a chemist, and what  
2 I did is I analyzed samples that we made. If I  
3 remember correctly, the company was an industrial  
4 chemical manufacturer. And I don't remember the  
5 products, I apologize. It's been a long time.

6 But I do remember we made different  
7 industrial-grade chemicals. And as a chemist, when I  
8 started there, I basically analyzed raw materials  
9 that came into the factory. I analyzed finished  
10 product.

11 There were also some intermediate  
12 chemicals, you know, in the process -- when we worked  
13 in the process in a plant. And so I would go and get  
14 the samples and analyze and, you know, and then give  
15 instructions to the manufacturing on how to proceed.

16 So now that you remind me, I think  
17 that's, actually now looking at the amount of  
18 chemistry and things that I do, I do need to add that  
19 to my CV, because I think it is relevant.

20 Sometimes you think those things, you  
21 really don't -- it didn't really make that much  
22 impact, but it is something, you know. I mean, I  
23 was, like I said, really helping to manage the  
24 manufacturing process of the company, in the  
25 manufacturing.

1 Q. So if I understand what you are saying is,  
2 you were a chemist and you were reviewing certain  
3 products of the company at different stages?

4 A. Yes.

5 Q. For quality or for --

6 A. Yes, the quality. I also --

7 Q. Go ahead.

8 A. -- provided the instructions. So, for  
9 example, you know, the process would stop and we  
10 would analyze the sample to determine whether we need  
11 to add more of something or if we need to heat it up  
12 more.

13 We had a whole algorithm that basically I  
14 was doing. I was kind of like a chemical engineer, I  
15 guess, because really I was helping controlling the  
16 manufacturing process.

17 Q. Were there other chemists that you worked  
18 with?

19 A. Yes.

20 Q. How many?

21 A. Oh, boy, I'm trying to remember.

22 Q. Were there --

23 A. So there were different shifts too, so, you  
24 know --

25 Q. Which shift did you work?

1 A. I worked on the first shift, but I helped out  
2 if there was a need for second or third, if they  
3 needed somebody to cover when somebody went on  
4 vacation.

5 Q. And you say you did that job full time  
6 between '97 and '99?

7 A. Yes.

8 Q. So was that your full-time employment during  
9 that period?

10 A. I believe so, yes.

11 Q. Is that company still in business?

12 A. I honestly am not sure.

13 Q. So from May of '97, when you got your degree,  
14 until May of '99, you were a chemist at Lindau  
15 Chemical.

16 Is that the name of the company, Lindau  
17 Chemical?

18 A. Lindau Chemicals, because they made all  
19 different kinds.

20 Q. Okay. Do you remember some of the chemicals  
21 they made?

22 A. They had the proprietary blends. It was not  
23 like a chemical like magnesium stearate or something  
24 that you find. It was something that you make. Like  
25 I said, that they made their own blends. You know

1       what I'm saying? These were --

2       Q.       And what were they used for?

3       A.       So I don't know the scope of all of them,  
4       because there are different kinds. Some of them were  
5       something that you make the plastics out of.

6               So they were -- one of them was some type  
7       of a plastic that you cure with heat. And you can  
8       make the -- I remember we had -- in the lobby of the  
9       company, we had like for a bow and arrow, the plastic  
10      handle that you hold. That plastic part was actually  
11      made from the products that we made.

12             So that was one of the things, one of the  
13      uses. And I think there are probably some other, you  
14      know, people that ordered similar products.

15      Q.       So in May of '99 you went to work for  
16      GlaxoSmithKline?

17      A.       Uh-huh.

18      Q.       And you list your position as senior  
19      pharmaceutical chemist; is that correct?

20      A.       I didn't start as a senior, because obviously  
21      when I started, I was just a chemist coming from a  
22      chemical company.

23             The senior pharmaceutical chemist,  
24      whatever the title is, it really was something that  
25      was the highest level that I had achieved.

1 Q. When you were a senior pharmaceutical chemist  
2 at GlaxoSmithKline, can you kind of tell me what you  
3 did day-to-day?

4 A. So I performed analysis of the products. I  
5 also helped with development, like, of the  
6 methodology. We had a product that we had to  
7 transfer -- we had a site transfer where a product  
8 came from one site, and we brought it to our site or  
9 to a different site. So you would have to do all of  
10 the paperwork and you have to do all of the method  
11 transfer.

12 So you have to, basically, take the  
13 methodology that was done at the original site, and  
14 when the product is transferred to your site, you  
15 basically show that you are capable to perform that  
16 same methodology at your site.

17 Q. What are you actually doing as the chemist?  
18 You know, GlaxoSmithKline, among other things,  
19 manufactures drugs; right?

20 A. Yes.

21 Q. So as the chemist -- as the senior  
22 pharmaceutical chemist, what is your role in that?

23 A. So depending. So in the sites where you are  
24 located, you basically, you know, analyze chemicals  
25 that come in that are used in manufacturing.

1 Or, you know, as I progressed in, you  
2 know, the range, like I started as a chemist doing  
3 analysis, and so, you know, I performed quality  
4 control testing of products. And then, you know, you  
5 get involved in other things, administrative type of  
6 things.

7 So, you know, I supported the internal  
8 audit team. I supported, like I said, the transfers  
9 of the products. But generally chemistry is one of  
10 the key skills that you need to have.

11 Q. So were you primarily just analyzing raw  
12 materials that were being used in the manufacture of  
13 drugs?

14 A. That was one of the things that I did, yes.

15 Q. Was that the primary thing that you did?

16 A. I didn't analyze just the raw materials. I  
17 also analyzed actual products.

18 Q. Okay. And you were analyzing the actual  
19 products for what purpose?

20 A. Quality control.

21 Q. Okay. And you indicate in your CV that you  
22 assisted with development of the internal audit  
23 system and issuance of appropriate protocols to  
24 assure compliance with, I guess, good manufacturing  
25 practices, USP 797; is that correct?

1 A. Yes, that's correct.

2 Q. How does USP -- for example, how did USP  
3 requirements apply to what you were doing as a  
4 chemist?

5 A. So the USP requirements really are applicable  
6 across the board. And that's just because the USP is  
7 a chapter that -- not a chapter. USP is a compendium  
8 that basically provides guidance for you, whether you  
9 work in industry or you work in health care as a  
10 pharmacist. The USP is just a set of guidelines and  
11 standards that, for example, the industry has adopted  
12 as a part of their quality measures.

13 Q. Was that your first exposure to USP  
14 requirements, in that production?

15 A. Yes. Absolutely, yes. Back then, actually,  
16 we still had the book. That tells you how long ago  
17 it was; we still had the book.

18 Today, I haven't seen a book. I was  
19 trying to get a book to show my students, because  
20 it's a really huge book. And I wanted to show my  
21 students in school in the College of Pharmacy how the  
22 book looks, and I could not even find a printed copy  
23 anymore. I said, I'll take an expired one, I just  
24 want one.

25 Q. I understand. And then from December -- so

1 you were there from May of '99 to December of 2004,  
2 and then you took a position with Pfizer?

3 A. Yes.

4 Q. As a senior pharmaceutical -- did you start  
5 off as the senior pharmaceutical formulation  
6 specialist?

7 A. I did. I was there a relatively short time,  
8 because I ended up going back to pharmacy school.  
9 And so I took the job, and basically it was a  
10 promotion. It was a better job, and so it was a good  
11 step for me. And Pfizer just was a better package,  
12 better from the perspective of what they offered for  
13 their employees. And so I --

14 Q. You said -- I'm sorry.

15 A. That's all.

16 Q. Okay. Was it essentially the same sort of  
17 position that you had with GlaxoSmithKline?

18 A. Very similar, yes.

19 Q. You were a chemist with Pfizer?

20 A. Yes.

21 Q. Doing different sorts of analysis and that  
22 type of thing?

23 A. Yes.

24 Q. So in the fall of '96 you left Pfizer and  
25 started pharmacy school; is that right?

1 A. Yes.

2 Q. As I read your CV, it looks like -- while you  
3 were in pharmacy school, it looks like you had two  
4 positions, two employment positions that sort of --  
5 while you were going through pharmacy school; is that  
6 right?

7 A. Yes, that's correct.

8 Q. You were a student intern at Rite Aid  
9 Pharmacy in Columbia, South Carolina, from September  
10 of '06 until May of 2010?

11 A. Yes.

12 Q. And then you also were a hospital pharmacy  
13 student intern at Lexington Medical Center, West  
14 Columbia, South Carolina, from June of '08, which I  
15 guess was like your third and fourth year of pharmacy  
16 school?

17 A. Yes. What happens, a lot of times -- well,  
18 what happened to me -- it doesn't happen a lot of  
19 times. But what happened to me is, after -- I worked  
20 at Rite Aid as a student intern, you know, worked in  
21 retail. And I honestly at the time thought retail  
22 was my calling, and so I enjoyed it.

23 So then after my second year of school,  
24 you go on another APP. They call it APP, which is  
25 advanced pharmacy practice experience. And so the

1 school sends you for a month to do an internship.

2 And so I went and had an internship in  
3 the hospital at Lexington Medical Center, and I  
4 absolutely loved it. And then so then I took on that  
5 job as an intern at a hospital.

6 And I still worked at Rite Aid, because I  
7 still liked the job at Rite Aid as well, and I really  
8 liked the people I worked with and so I didn't want  
9 to leave that. And so from there on I had two jobs.

10 It seems like it's a lot to manage, but  
11 actually it was very -- it was really well balanced,  
12 because I was able to work during the week in the  
13 shorter spurts in retail, which is common. You can  
14 just work three or four hours, so I was able to do  
15 that around my school schedule.

16 And then the hospital requires typically  
17 for me to work -- or required a time for me to work  
18 full shift as in eight hours, and so I worked on the  
19 weekends at the hospital.

20 Q. When you were working as a student intern at  
21 Rite Aid, are you just like filling prescriptions and  
22 dealing with customers, is that fair?

23 A. Yeah. You basically shadow a pharmacist, and  
24 so you learn about, you know, what a practitioner  
25 does. You help with counseling, filling. You help

1 with ordering. You help with -- you support the  
2 pharmacist's efforts.

3 Q. Was there any compounding done at that Rite  
4 Aid Pharmacy?

5 A. There was very little. It's not sterile, of  
6 course. This was a nonsterile compounding per USP  
7 795. And this is where my chemistry skills came in  
8 really handy, because I was very comfortable with  
9 weighing and measuring.

10 Q. Got you. So you did some of that at Rite  
11 Aid?

12 A. Uh-huh.

13 Q. Okay. And what kind of work did you do at  
14 the hospital?

15 A. Well, I really was inclined towards the  
16 sterile compounding, because it was very comfortable  
17 and similar to what I have done working in industry  
18 where you work with medications directly, you prepare  
19 them.

20 And so I worked in a cleanroom,  
21 compounding medications for patients, preparing  
22 things, even complex things like chemotherapy  
23 batching. So I would make these really large-scale  
24 batches of medications, but I also supported any  
25 other efforts.

1           So if they needed me to do any other work  
2 as a pharmacy intern, whether it was filling the  
3 Pyxis machines or whether it was, you know,  
4 delivering medications, I did whatever was needed.

5           But I did have preference for cleanroom,  
6 and when I had a chance, if there was an opportunity  
7 for me to work in the cleanroom, I was definitely  
8 always up for it.

9           Q.       So you were doing -- were you doing sterile  
10 compounding at the hospital?

11          A.       Yes.

12          Q.       And as a student intern, how does -- how are  
13 you able to do that?

14          A.       You are able to because you are being  
15 overseen by the pharmacist. So as long as you are,  
16 you know, supervised by a licensed pharmacist, you  
17 are -- as an intern you can compound, the same way as  
18 the pharmacy technicians do.

19          Q.       And you got your PharmD degree in 2010?

20          A.       Uh-huh.

21          Q.       At the University of South Carolina; is that  
22 right?

23          A.       That's correct.

24          Q.       And then you also got a master of science in  
25 pharmacy in 2010 in pharmaceutical chemistry?

1 A. That was a good year.

2 Q. It was a good year.

3 A. I got two advanced degrees in the same year.

4 Q. Yeah. How did you do -- how did that work?

5 A. So the way this actually worked, it's really  
6 interesting, because I worked -- I had my -- when I  
7 was at GlaxoSmithKline, I actually started on this  
8 program with a master's degree in pharmaceutical  
9 chemistry. So I started all of this, we are talking  
10 way back when I was at Glaxo.

11 And at the time I already knew I wanted  
12 to pursue a graduate degree, and so I was kind of  
13 slowly chipping away on some of the courses that I  
14 could do in this program.

15 And so I took some courses, and then  
16 actually when I went to Pfizer, Pfizer, I believe,  
17 offered to pay for some of the coursework. And so  
18 when I worked at Pfizer, I continued on it.

19 So then when I got into pharmacy school,  
20 I was able to transfer some of the courses because  
21 there are overlapping, as in I took pharmacology at a  
22 pharmacy school, and it's the same pharmacology  
23 course that I would need for my master's degree. So  
24 I was able to transfer probably about four or five  
25 courses towards the program, towards my master's

1 degree. And then I had to take, I think, two or  
2 three more classes.

3 So I graduated in May from PharmD. And  
4 then I worked on my coursework, and basically was  
5 able to complete my pharmaceutical chemistry degree  
6 in December. So it was fantastic. It was one of the  
7 best years of my life. I graduated twice that year.

8 Q. Was the work at the University of Florida --  
9 was that remote learning?

10 A. The majority, yes, thankfully. I had to go  
11 there. There are some things I had to go there for.

12 Q. Like what?

13 A. They had a course that I had to attend that  
14 was in person.

15 Q. And was this while you were in pharmacy  
16 school or while you were --

17 A. No, that was after. That was the last  
18 course -- sorry, my dog.

19 That was the last course I took, and it's  
20 basically as the final exam. So you take all this  
21 coursework online, but you have to come and take the  
22 last course in person. And you take this humongous  
23 exam that basically tests, making sure that all of  
24 the other courses that you have done distant, that  
25 you actually did.

1                   So you have -- I mean, the exam is -- I  
2   think it was a four-hour exam and it was very  
3   difficult. And it was questions in pharmacology,  
4   medicinal chemistry, all of these courses that I took  
5   over a period of years, and so you basically have to  
6   show proficiency.

7   Q.           How many hours is that master of science  
8   program?

9   A.           Gosh, I do not remember. I would have to go  
10   and look.

11   Q.           Do you have a rough guess?

12   A.           I am sorry, I do not.

13   Q.           Is it more than 20?

14   A.           How many credit hours, are you asking?

15   Q.           Yes.

16   A.           I am not sure. I think so. I mean, it is a  
17   standard. You can look online. It is a master's in  
18   pharmaceutical chemistry. You can look online at the  
19   University of Florida.

20   Q.           You say you had an industrial pharmacy focus;  
21   what does that mean?

22   A.           Yes. So there are a couple of different  
23   tracks, because you have electives that you take  
24   within that course, within that degree. So you can  
25   kind of, you know, focus on what are some of the

1 coursework, because, you know, some students in that  
2 class were focusing more on like management, and some  
3 of us really focused more on the industry. And so  
4 that was my interest, was really focusing on  
5 industry.

6 Q. So what is industrial pharmacy, what does  
7 that mean?

8 A. So you learn more about some of the general  
9 regulations like quality control, where do those  
10 guidances come from, and how would you create them if  
11 you were opening your own. Or how can you  
12 effectively manage, maybe, your, like, raw materials,  
13 maybe a new raw material or product development, and  
14 so you need to develop quality procedures to put in  
15 place.

16 And so this is where you would -- you  
17 know, if you have this education, you know, what are  
18 the correct steps, how would you do that.

19 Q. And this may sound like a dumb question, but  
20 is that like -- are you talking about the pharmacy  
21 industry, or are you talking about -- when I think of  
22 industrial pharmacy, I think of Big Pharma --

23 A. Yes.

24 Q. -- as like Pfizer and Abbott, that kind of  
25 thing. Is that what that is?

1 A. Yes, that's exactly what it is. You  
2 basically are --

3 Q. As opposed to how to run a Rite Aid?

4 A. Yes, exactly.

5 Q. Okay. Am I right that the PharmD degree, is  
6 that the current entry level degree for all  
7 practicing pharmacists?

8 A. Yes.

9 Q. And has been since about 2004; is that right?

10 A. I do not know the exact year, but, yes, it  
11 has been a while.

12 Q. It's a four-year degree?

13 A. Yes.

14 Q. And so the pharmacists at Kroger -- if I go  
15 to Kroger and get a prescription, if they graduated  
16 after a certain point in time, they have a PharmD  
17 degree; is that right?

18 A. Yes.

19 Q. Let me ask you this. Would you say that most  
20 people who get a PharmD degree either practice in the  
21 area of clinical pharmacy like prescribing and  
22 filling prescriptions for patients, or the industry  
23 of bringing medications to market?

24 A. So I would say I believe -- and I'm not  
25 100 percent sure of the statistics, but somewhere in

1 the 70 percent-something range percentage of  
2 pharmacists works in retail.

3 So those are the pharmacists exactly as  
4 you mentioned, folks working in Rite Aid, folks  
5 working in Kroger. And they have a small, slim  
6 chance -- proportion of pharmacists who work clinical  
7 as in hospital, or maybe -- in nursing homes you have  
8 to have consulting pharmacists, so you will have the  
9 small percentage of those pharmacists.

10 So, yes, the majority does work in  
11 retail. And there is a small proportion that works  
12 in hospitals, and then there's still a small  
13 proportion of pharmacists who are working in  
14 industry.

15 Q. All right. So as I read your CV, after you  
16 got your PharmD degree in 2010, you had two jobs.  
17 One was a PRN pharmacist.

18 And correct me if I'm wrong, does PRN  
19 pharmacist mean basically as needed?

20 A. Yes.

21 Q. So you worked sort of as needed from 2010  
22 through August of 2012 --

23 A. Yes.

24 Q. -- at Rite Aid?

25 A. Yes.

1 Q. Is that the same Rite Aid you worked at while  
2 you were in pharmacy school?

3 A. No, you have to float. When you don't take a  
4 full-time position, they usually don't need you in  
5 the same store, so you are going to be a floater. So  
6 you just get sent to whichever store needs a  
7 pharmacist at that time.

8 Q. So you were a PRN pharmacist for Rite Aid  
9 from September of '10 to August of 2012.

10 A. I was, but that's officially when I kind of  
11 stopped. I don't think I worked there much, because  
12 it was just -- you know, I had a full-time job. I  
13 was already a faculty member at a university. And  
14 so, honestly, these PRN jobs -- this is before I had  
15 children and I had time on the weekends.

16 Q. I understand.

17 A. So at that time I would work extra, because I  
18 had a lot of student loans that I needed to pay off.

19 Q. And so that's -- so that's what I wanted to  
20 get at.

21 So between -- really in the fall of '10  
22 to the fall of 2012, you were working PRN pharmacy at  
23 Rite Aid and PRN pharmacy for UnitedHealthCare?

24 A. Yes.

25 Q. Right? And those were part-time jobs?

1 A. Yes.

2 Q. And tell me about the PRN pharmacy job for  
3 UnitedHealthCare. What were you doing for them?

4 A. So I was a consulting pharmacist, so I worked  
5 in -- it's a small pharmacy, and I'm not even sure if  
6 they are still around. I think they got bought out  
7 by somebody.

8 But it was a small pharmacy that  
9 basically -- what they did is they managed nursing  
10 homes. And so what we would do, is I worked on the  
11 weekends strictly and we would do the -- you know,  
12 when a patient -- most of the patients that come into  
13 the nursing homes get admitted on the weekdays. So  
14 weekends we just kind of maintain status quo. You  
15 don't get that many orders on the weekends. So we  
16 would verify orders if needed, and then fill  
17 prescriptions for patients who got admitted over the  
18 weekend.

19 Also sometimes it involved, you know,  
20 communication with a hospital, because we would have  
21 to double-check if the orders are correct, so  
22 consulting pharmacists. I would oversee operations.  
23 I would be the only pharmacist there --

24 Q. Okay.

25 A. -- sometimes.

1 Q. So from the time you graduated in 2010 until  
2 the fall of 2012, your primary job was an academic  
3 position?

4 A. Yes.

5 Q. And that was at South University --

6 A. Yes.

7 Q. -- was your pharmacy?

8 A. Yes.

9 Q. That's also not South Carolina University?

10 A. That's right. It's confusing, I know.

11 Q. So South University is another pharmacy  
12 school?

13 A. Yes. It's a private small school, yes, for  
14 pharmacists.

15 Q. Columbia, and they also have a campus in  
16 Savannah; is that right?

17 A. That's correct.

18 Q. And so that was your full-time job?

19 A. Yes.

20 Q. And you took that -- so you took that job  
21 right after you got your PharmD degree?

22 A. Yes.

23 Q. Have you ever been a full-time pharmacist,  
24 practicing pharmacist?

25 A. Well, I work at the Palmetto Health Richland

1 as a pharmacist; not full time. So I guess not full  
2 time.

3 Q. Yeah. But since you graduated with your  
4 degree, have you ever been a practicing full-time  
5 pharmacist?

6 A. Well, according to South Carolina Pharmacy  
7 Practice Act, in South Carolina a teaching pharmacy  
8 is considered practicing pharmacy, so I guess the  
9 answer would be yes.

10 Q. Okay. Other than -- but your primary job is  
11 not -- you are primarily teaching pharmacy students,  
12 that's your main job, right?

13 A. Yes.

14 Q. And it has been since you graduated from  
15 pharmacy school?

16 A. Yes.

17 Q. And your part-time positions?

18 A. Right.

19 Q. Right? Is that correct?

20 A. I'm sorry. You got -- I didn't hear what you  
21 said, the last part.

22 Q. You have had part-time positions working as  
23 a, I guess, retail or clinical, however you want  
24 to -- different positions, but your primary job since  
25 you got your PharmD degree has been as an academic,

1 right?

2 A. That's correct.

3 Q. Okay. And that you worked as an assistant  
4 clinical professor at South University from May of  
5 2010.

6 Is that like right after you got your  
7 degree?

8 A. It is.

9 Q. So you graduated in May of 2010, and you took  
10 a position as an assistant professor of clinical and  
11 pharmaceutical studies at South University, and you  
12 did that for three years until August of '13?

13 A. That's correct.

14 Q. Okay. And tell me what you -- and your PRN  
15 work, was it strictly weekend work?

16 A. Yes.

17 Q. Okay. So tell me, if you would, day-to-day,  
18 say May of 2010 after you graduated from pharmacy  
19 school to August of '13, day-to-day, what were  
20 your -- what were you doing?

21 A. You mean teaching at the university at South,  
22 what I did at South?

23 Q. Yeah. Kind of give me the day in the life of  
24 Dr. Michaela Almgren for those three years; what were  
25 you doing?

1 A. I was very busy. I was teaching a variety of  
2 courses, had to develop a lot of my own teaching  
3 materials. When I started there, I taught, you know,  
4 just a couple courses, because, you know, I really  
5 didn't have a teaching portfolio at the time. I kind  
6 of had to develop my lectures. And so I started  
7 just, you know, mostly helping -- coordinating the  
8 courses.

9 And then I started teaching. I took on a  
10 really large teaching load. I took over one of the  
11 most consuming courses, the pharmaceutical  
12 calculations. And so I would go every day to work  
13 and basically work on developing my teaching  
14 materials.

15 I precepted some students. I tutored  
16 students. I helped with teaching labs; really a  
17 variety of things that I do on a day-to-day basis.

18 Q. So I want to ask what may seem like a silly  
19 question, but how does a -- how does a person who has  
20 never really been a pharmacist start just teaching  
21 pharmacy?

22 I mean, you went to pharmacy school and  
23 got your pharmacy degree. How do you just turn  
24 around and start teaching pharmacy when you have  
25 never been a pharmacist?

1 A. Well, keep in mind that about half of faculty  
2 at universities do not have a PharmD. We have PhDs  
3 at our college that are not pharmacists.

4 So in my college right now at the  
5 University of South Carolina, many of my colleagues  
6 are not practicing pharmacists, because they teach  
7 subject matters that are not necessarily pharmacy  
8 practice related.

9 So, you know, I did not teach directly,  
10 you know, things that I would not know anything  
11 about. But, for example, sterile compounding, I have  
12 done that as a student.

13 And, you know, when you are -- when you  
14 learn as a student to perform sterile compounding,  
15 you know, it is the same on the level -- I mean, I do  
16 the same things that a pharmacist would. So I  
17 experienced sterile compounding, for example.

18 Pharmaceutical calculations, do you  
19 really need to be a pharmacist? I mean, this is a  
20 course that can be taught by a PhD, by somebody that,  
21 you know, has understanding of how to calculate.

22 So I don't think that you -- it depends,  
23 of course, on your level of expertise on subject  
24 matter, but there are definitely areas that you can  
25 teach and you don't have to be a pharmacist or a

1 practicing pharmacist, you just have to have an  
2 in-depth knowledge.

3 Q. In your CV where you talk about you are  
4 assistant professor of clinical and pharmaceutical  
5 studies, you say you taught the majority of  
6 hospital-related lab class work, including TPN  
7 compounding, IV and chemical -- I'm sorry, IV and  
8 chemotherapy preparation and USP 797 training.

9 Is your compounding experience, your  
10 sterile compounding experience related to pharmacy,  
11 what you learned in pharmacy school, plus what you  
12 learned in your internships?

13 A. Absolutely that, and also I took some other  
14 courses. I took -- there was a course that was  
15 offered through -- I think it's called Critical -- I  
16 think they are called Critical Point. It's a company  
17 that offers this in-depth sterile compounding  
18 training. I took that.

19 I take a number of continuing education  
20 courses every year to further my understanding of  
21 sterile compounding. You know, truth be told,  
22 sterile compounding, it's a very unique area of  
23 pharmacy.

24 And I can tell you there are a lot of  
25 pharmacists out there who have never done sterile

1       compounding, so it's something that's unique.

2                       (WHEREUPON, a document was marked as  
3       Exhibit Number 5.)

4       BY MR. SUTHERLAND:

5       Q.       I want to go back to 2010, though, when you  
6       graduated from pharmacy school.

7       A.       Uh-huh.

8       Q.       You began teaching about compounding. And  
9       what I want to know is, where did you get the sterile  
10      compounding experience that you were starting to  
11      teach in May of 2010; where did that come from?

12      A.       Well, I was a pharmacy intern in the  
13      hospital, and so I performed sterile compounding  
14      there. You know, you perform it under USP guidelines  
15      under USP Chapter 797 under the guidance of  
16      pharmacists, and you work side-by-side with the  
17      pharmacists.

18      Q.       And those were part-time positions while you  
19      were in pharmacy school?

20      A.       Yes.

21      Q.       Okay.

22                       MR. SUTHERLAND: Lynne, I think,  
23      Dr. Almgren, we have been going for about an hour and  
24      40 minutes. If it's okay, why don't we take about a  
25      10-minute break.

1 MS. LEONARD: That sounds fine to me.

2 MR. SUTHERLAND: Then we'll come back and  
3 get started again.

4 MS. LEONARD: I guess 10:47, I guess,  
5 something like that for you?

6 MR. SUTHERLAND: Let's just say 10:50,  
7 11:50 Eastern.

8 MS. LEONARD: Great. Thank you.

9 (An off-the-record discussion was held.)

10 BY MR. SUTHERLAND:

11 Q. Dr. Almgren, you are on mute, so I'm going to  
12 remind you -- thank you.

13 We were talking about your CV and your  
14 experience. And when we broke, I had -- we talked  
15 about you graduated from pharmacy school in 2010, and  
16 your full-time job after you graduated was an  
17 academic position with South University College of  
18 Pharmacy. And then you worked for a couple of years  
19 on the weekends, as you have described it, either for  
20 Rite Aid or for UnitedHealthCare; is that accurate?

21 A. Yes.

22 Q. And then in 2013 -- oh, I left something off.

23 You were also -- you also list adjunct  
24 faculty at University of Florida Distance Program,  
25 University School of Pharmacy, January '11 to May

1 '14. So that was just you were teaching remotely for  
2 the University of Florida?

3 A. That's correct.

4 Q. And then in the fall of 2013 you went back to  
5 the University of South Carolina; is that right?

6 A. That's correct.

7 Q. In another academic position as a clinical  
8 assistant -- I'm sorry, no.

9 As a clinical assistant professor at the  
10 University of South Carolina College of Pharmacy,  
11 right?

12 A. That's correct.

13 Q. And you have been doing that until the  
14 present?

15 A. Yes.

16 Q. You also during that time have had a couple  
17 of other jobs, and I want to talk to you about all of  
18 it. But your full-time job is teaching, right?

19 A. Yes.

20 Q. And has been -- well, it has been since you  
21 graduated from pharmacy school, but since '13 at the  
22 University of South Carolina College of Pharmacy?

23 A. Correct.

24 Q. You also list two part-time jobs -- well, I  
25 shouldn't say part-time. You tell me.

1                   From 2013 to 2018, you were a hospital  
2 pharmacist for Palmetto Health Richland Hospital,  
3 correct?

4           A.       Yes, correct.

5           Q.       And first of all, was that a part-time  
6 position?

7           A.       No. The way that this works is, typically in  
8 professional type of programs like the College of  
9 Medicine, College of Pharmacy, a lot of times the  
10 faculty has a dual appointment.

11                   And so this is what hospital pharmacists  
12 and the outsourcing pharmacists -- both of those  
13 positions are basically part of my full-time job. So  
14 I split my work. I'm not at the college full time.

15                   I split my work hours between hospital --  
16 initially, it was between hospital, between Palmetto  
17 Health and the university.

18                   And then there was an open opportunity  
19 that I took because I felt it fit better my  
20 qualifications, and now I work as an outsourcing  
21 pharmacist and, again, as a part of my faculty  
22 appointment.

23                   So I'm actually half the time at the  
24 college, and half the time at the -- wherever your  
25 position, your dual appointment is. So I am a

1 hospital pharmacist and I work for a hospital as, you  
2 know, a regular part of a hospital team as a regular  
3 pharmacist, and I was teaching.

4 Q. So let's talk about the position of hospital  
5 pharmacist at Palmetto Health Richland Hospital  
6 Pharmacy, Columbia, South Carolina, August of '13 to  
7 September of '18.

8 So from the fall of '13 when you took the  
9 position as a professor at the University of South  
10 Carolina College of Pharmacy, until September of '18,  
11 you are splitting these duties.

12 And what I'd like to know, if you can  
13 help me, is what does a day-to-day, week-to-week,  
14 month-to-month look -- what does your work look like?  
15 That would be helpful.

16 A. So as a faculty member, when I got hired in  
17 August of 2013, I was teaching in the health systems  
18 pharmacy labs. And that course ran Tuesday,  
19 Wednesday and Thursday from 1:30 to 4:30.

20 And I was actually teaching everything  
21 that's related to hospital pharmacy practice. So  
22 sterile compounding, you know, compounding, sterile  
23 compounding, anything that relates to that area.  
24 And, of course, hospital practice, how you review  
25 orders, how you fill prescriptions in a hospital

1 setting, what goes on a prescription, what are some  
2 of the regulations.

3 So I did that on Tuesday, Wednesday and  
4 Thursday. And then my Mondays and Fridays I was at a  
5 hospital working as a hospital pharmacist, just like  
6 all of the other pharmacists in that position.

7 So I would work in a cleanroom, depending  
8 on what your assignment for the day was. And there  
9 is a schedule that you would go to and you could see,  
10 okay, you know, I'm working in a cleanroom, or I'm  
11 verifying orders, or I'm verifying orders in a  
12 cleanroom. You know, whatever the assignment was, is  
13 where I was located for the day, and that would be my  
14 Mondays and Fridays. So Monday and Friday was  
15 hospital; and then Tuesday, Wednesday, Thursday was  
16 university.

17 Q. Okay. And that was the way it was -- that's  
18 the way it started, but was it that way every  
19 semester?

20 A. Yes, spring and fall. It was two separate  
21 courses. So there's an Introduction to Health  
22 Systems Pharmacy, which is a full course for the P2  
23 year. And so I would teach the introduction in the  
24 fall, and in the spring semester it was Advanced  
25 Health Systems Pharmacy.

1 Q. Did you --

2 A. I'm sorry.

3 Q. Go ahead.

4 A. What I was going to say, that pattern  
5 continued spring and fall. And in the summer I would  
6 just work two days in the hospital, and it didn't  
7 have to be Monday and Friday. It could be other days  
8 at that point because I didn't have class.

9 And then the rest of the time I was at  
10 university trying to revamp the course and, you know,  
11 make sure that I have sufficient supplies and kind  
12 of, you know, get things together for the class.

13 Q. All right. And was that the way it was from  
14 August of '13 until September of '18?

15 A. That's when I do the labs.

16 Q. So I guess my question is, for that five-year  
17 period, or '13 to '14, '14 to '15, '15 to '16, '16 to  
18 '17, '17 to '18, you were Monday and Friday in the  
19 hospital, Tuesday, Wednesday, Thursday at school?

20 A. I think what happened, about two years in the  
21 contracts stayed the same, but my days shifted  
22 around, because what happened is there was another  
23 course that was being taught at university that  
24 needed the lab on Thursday, and so we had to switch  
25 the lab to move it to be taught Monday, Tuesday,

1 Wednesday, so it changed the schedule, so then I  
2 would be in the hospital Thursday and Friday.

3 Also, my contract changed in the sense  
4 that I ended up switching. Instead of having two  
5 days in the hospital and then three days in the lab,  
6 what I did instead is I ended up still having the  
7 same amount of time contract-wise, I believe, you  
8 know, in the hospital, just change it where I would  
9 work in a hospital in the summer a little more to  
10 make up for the time that I was out.

11 You know, I would only work one day a  
12 week in the hospital instead of two, because it was  
13 really difficult to manage the course. When you  
14 think about it, you have 110 students three days a  
15 week, managing, you know, the supplies, the grading.  
16 I mean, the labs have a lot of paperwork that the  
17 students submit. It's a very busy course. There are  
18 quizzes. There are exams.

19 And so if you are two days in the  
20 hospital and then three days in university, you  
21 really have no time to regroup. And you have to set  
22 up the lab, which is practicals, for the next week.

23 And so I always felt extremely frazzled,  
24 because, you know, you are always on the go. You are  
25 either in the hospital or you are in the college, and

1 when you are in the college you are teaching, and so  
2 I really never had time to regroup.

3 And so I requested of the college if they  
4 could change things around so I could have more time  
5 at the college, and then one extra day to regroup,  
6 change things around, you know, for the lab to get  
7 things together, and then move on the next week, you  
8 know, and then just go from there.

9 Q. So that I understand, for the first two years  
10 you were a professor at the University of South  
11 Carolina. Two days a week you were working at the  
12 hospital. Three days a week you were at the  
13 university?

14 A. Yes.

15 Q. And then in the summer you worked two days a  
16 week in the hospital, and the rest of the time at  
17 school --

18 A. Yes.

19 Q. -- doing preparation work?

20 And then in your third year you cut back  
21 your time in the hospital to account for increased  
22 coursework?

23 A. Yes.

24 Q. Course preparation work?

25 A. Yes.

1 Q. One day in the hospital, and then maybe a  
2 little more time in the summers?

3 A. Yes.

4 Q. Okay.

5 A. So in the summer I would be in the hospital  
6 two days as doing the contract, but I would try to  
7 make up those one days that I missed during semester.  
8 We would spread them out over summer.

9 Q. And so you would go to the hospital, and who  
10 would -- were you working under the direction of  
11 somebody at the hospital?

12 A. Yes.

13 Q. And who would that be?

14 A. So there was a different manager. When I  
15 started, Jennifer Bayer was my direct supervisor.  
16 And she was more or less a supervisor for the  
17 department the rest of the time too.

18 There were direct supervisors that would  
19 change, because people came and go, but Jennifer  
20 Bayer was the one that was really supervising the  
21 operations.

22 Q. I apologize. I'm not asking for you to tell  
23 me their names. I don't really need to know their  
24 names. But the position of the person that was  
25 supervising your work at the hospital was who? What

1 was the position; the pharmacy director?

2 A. No, it was not pharmacy director. Well, the  
3 pharmacy director is the one who oversees that whole  
4 department. I believe it's called lead pharmacist.  
5 Lead pharmacist is who does the scheduling and  
6 managing of the hours.

7 Q. All right. And so you were being directed by  
8 the lead pharmacist at the hospital?

9 A. Yes.

10 Q. And you'd just do whatever they needed you to  
11 do the days you were there?

12 A. Yes.

13 Q. All right. And did that involve dispensing  
14 medication?

15 A. Sure.

16 Q. Filling prescriptions --

17 A. Yes.

18 Q. -- for patients at the hospital?

19 A. Yes.

20 Q. Counseling patients?

21 A. Sometimes, yes.

22 Q. What would you say the majority of the work  
23 at the hospital is or was during that period,  
24 five-year period? The majority of the day you are  
25 there, what are you doing?

1 A. Probably verifying orders, reviewing orders,  
2 medications.

3 Q. And so that's how that went until September  
4 of '18; is that right?

5 A. Yes.

6 Q. Okay. Then you took this position with  
7 Nephron Pharmaceuticals Company?

8 A. Yes.

9 Q. Tell me about Nephron Pharmaceuticals  
10 Company.

11 A. So at Nephron I am a clinical advisor, so I  
12 work more in the drug development area. So it kind  
13 of goes back to my roots of coming from the Pharma.

14 And what I do is I help with whenever we  
15 have -- for example, we are a 503B compounding  
16 company, so it is a compounding pharmacy.

17 Nephron is a 503B outsourcing facility,  
18 and so we are a compounding pharmacy. We perform  
19 aseptic compounding. All of our products that we  
20 make are injectables.

21 I help with a lot of different tasks.  
22 You know, you have to keep in mind, when I started,  
23 we just started the outsourcing. Like, it was not in  
24 operation that long, so there was a lot of tweaking  
25 going on in terms of standard operating procedures,

1 in terms of formulation procedures. And so I helped  
2 with development of some of those.

3 I helped with -- nowadays, we have come a  
4 long way, and we definitely have a lot of this now  
5 already figured out in terms of how to do things in  
6 the best way to follow CGMP.

7 Q. Let me stop you for just a second. So in  
8 September of '18 to the present -- and I'm going to  
9 get into some of the details. But from September '18  
10 to present, you have been part time, or I guess  
11 full-time academic with this part-time component of  
12 outsourcing pharmacists and clinical specialists,  
13 right?

14 A. Correct.

15 Q. Like you said before. So tell me, does it  
16 work similarly?

17 A. Yes.

18 Q. How does it work between, you know, your  
19 teaching and what you do -- like, what you do  
20 day-to-day?

21 A. It's very similar to what I have described  
22 previously. So I'm in my practice side portion of  
23 the week and I'm at the university a portion of the  
24 week.

25 Q. Give me a little more detail. How many days

1 are you teaching? And then when you are not teaching  
2 at the university or doing teaching work, where are  
3 you and what are you doing?

4 A. So it really depends. So some weeks I'll be  
5 more at Nephron, and then some weeks I'll be more at  
6 the university. It really depends on my teaching  
7 schedule.

8 Q. Okay. Has it been variable since you started  
9 at Nephron?

10 A. Yes.

11 Q. About how much time percentage-wise are you  
12 at school and how much percentage at Nephron; is it  
13 50/50?

14 A. It's supposed to be 50/50. But I'm probably  
15 more at Nephron, because I also precept. So I do  
16 clinical teaching, meaning I have my pharmacy  
17 students with me, so that's another component of  
18 teaching that I do now on a larger scale.

19 I precepted before, but I precept on a  
20 much larger scale now. So what I do is I have  
21 pharmacy students every month, and this is a part of  
22 their required curriculum.

23 So, as I was mentioning earlier, the  
24 APPE, the Advanced Pharmacy Practice Experience, this  
25 is in order for the pharmacy students to be licensed

1 to be pharmacists. They have to have a certain  
2 number of hours that they complete as a part of their  
3 rotations, the clinical rotations.

4 And so part of their training in their  
5 last year of pharmacy school are these clinical  
6 rotations. And so they come with me to Nephron and  
7 they basically spend an entire calendar month working  
8 on different projects. They shadow me and they  
9 shadow on some of my other co-preceptors as well.

10 Q. One question I forgot to ask you, when you  
11 were -- for both of these situations. So when you  
12 are the hospital pharmacist at Palmetto Health  
13 Richland Hospital Pharmacy, were you a hospital  
14 employee?

15 A. No. I don't believe -- well, I'm not really  
16 sure in terms of exact employment arrangement there,  
17 but I think it's something along the lines of the  
18 university has a contract with the hospital, because  
19 I did have a badge at the hospital.

20 I did have -- you know, I am a part of --  
21 you know, I appear to be like a regular employee, so  
22 I have to follow all of the policies and procedures  
23 at the hospital, have to go to all of the training  
24 that a hospital requires. So I'm assuming, from that  
25 perspective, yes.

1 Q. Do you get paid by the hospital?

2 A. The hospital pays directly to the university,  
3 and I am considered a university employee.

4 Q. So is your salary -- do you have a salary for  
5 your professor position and do you get paid  
6 separately, are those distinct components, or you  
7 just have one salary?

8 A. It's just one.

9 Q. Okay. So there's no -- is it the same with  
10 Nephron?

11 A. Yes.

12 Q. So you are not an employee of Nephron?

13 A. I don't know technically how that works  
14 because, again, I have a badge. I have to follow  
15 their requirements in terms of all of the employee  
16 requirements. I have to go to training. Whatever  
17 policies they have, I follow all of them.

18 Q. So do all pharmacy professors do, sort of,  
19 part-time things where they are working for hospitals  
20 and pharmaceutical companies?

21 MS. LEONARD: Object to the form. You  
22 can answer.

23 BY MR. SUTHERLAND:

24 Q. Are you aware of other pharmacy professors  
25 who do similar work to what you are doing?

1 A. Absolutely. The majority of my colleagues  
2 does, yes.

3 Q. Okay. And so in the case of Palmetto Health  
4 Richland, you were aware that they were paying the  
5 university for your work?

6 A. Yes.

7 Q. And the same with Nephron, they pay the  
8 University of South Carolina for your work there?

9 A. Yes.

10 Q. Okay. So you are not compensated in any way  
11 by Nephron Pharmaceuticals Company?

12 A. No. If I wanted to work separate -- let's  
13 say if I wanted to get another position, you know,  
14 that would be different. But as a part of what I  
15 have, my clinical assignment, I am not directly  
16 compensated.

17 Q. When you go to the company, most of the time  
18 you are going by yourself, right, to work there, when  
19 you go to work at the company?

20 You mentioned taking students with you,  
21 but most of the time you are going out there and  
22 doing work for them by yourself; is that right?

23 A. Truth be told, I have my students with me  
24 probably nine out of 12 months.

25 Q. Every time you go to the company?

1 A. They are there.

2 Q. Okay. And so you said that Nephron is a 503B  
3 compounding pharmacy. Tell me, what is a 503B  
4 compounding pharmacy?

5 A. So 503B compounding pharmacy is a type of  
6 pharmacy where you can compound medications on a  
7 larger scale. You have to follow CGMP requirements,  
8 of course, but you don't have to have a prescription.

9 So that is a part of the DQSA of 2013,  
10 the law that was passed due to the NECC, the New  
11 England Compounding Center.

12 Q. I'm going to stop you because you are using  
13 lots of initials and acronyms here.

14 So you said that a 503B does large-scale  
15 compounding and has to comply with CGMP. What's  
16 that?

17 A. Current Good Manufacturing Practices.

18 Q. Okay. And it was -- the CGMP was based  
19 upon -- as part of what? I think the DQ --

20 A. -- SA, Drug Quality and Safety Act [sic] of  
21 2013.

22 Q. Go ahead.

23 A. That's all.

24 Q. So you have to comply with CGMP, it's part of  
25 the Drug Quality Safety Act. And what else that

1 would encompass a 503B compounding pharmacy?

2 A. So before 2013, the New England Compounding  
3 Center, that was another acronym I used, the NECC,  
4 New England Compounding Center, was a compounding  
5 pharmacy in Massachusetts that had produced  
6 large-scale batches of medications, and they sold  
7 them to pharmacies.

8 These drugs were contaminated because  
9 they did not use proper aseptic technique, and many  
10 patients were harmed and even died. And so because  
11 of that, this DQSA Act was passed, because we have  
12 such a severe drug shortages right now in the health  
13 systems in general.

14 There are just medications that are  
15 unavailable, and the patients need them. And a lot  
16 of times these medicines don't have another  
17 alternative, they are the only medicine that you can  
18 use.

19 And so because of that, this DQSA was  
20 passed, which allows pharmacies to do -- pharmacies  
21 to do large-scale compounding.

22 So up until 2013, you could only compound  
23 per USP 797 according to 503A regulations. And so  
24 with the passage of the DQSA Act, now we have an  
25 alternative.

1 And so you have pharmacies that can  
2 practice pharmacy and compound on a large scale as  
3 per 503B regulations, so those prescriptions -- those  
4 medications do not require a prescription.

5 So if you are going to compound for a  
6 503A, you have to have a patient-specific  
7 prescription. If you are compounding for 503B, you  
8 do not have to have a patient prescription. You  
9 compound just a general large amount of medication.  
10 You can make big batches, and then sell those.

11 Q. How big?

12 A. They can be anywhere -- it really depends on  
13 the size of the pharmacy. So there is no -- I don't  
14 know that there is any, you know, guidance on the  
15 minimum, but most of the time it can be in the  
16 thousands.

17 You just have to follow -- you just have  
18 to follow CGMP requirements, so you have to put in  
19 place quality and safety measures to make sure that  
20 the entire batch produced is safe.

21 Q. So if I understand correctly, so there are  
22 503A compounding pharmacies, which are like sort of a  
23 retail pharmacy that does small batch compounding  
24 based on a specific prescription from a provider to a  
25 patient, right?

1 A. Correct.

2 Q. And the 503B does large-scale compounding  
3 that provides medications for multiple patients, and  
4 is that through a retail pharmacy? Do you-all sell  
5 to retail pharmacies?

6 A. No, you sell directly to the hospital.

7 Q. So Nephron's products are sold to hospitals?

8 A. Yes. Now, we also have a manufacturing  
9 division, because Nephron has a tradition -- they  
10 have been in the business before the 503B was even  
11 around.

12 And Nephron is a manufacturer of  
13 albuterol, ipratropium, so some of the inhalation,  
14 also sterile preparations. So they have been around,  
15 and that was the main core business with them for  
16 years.

17 Q. There's a Nephron compounding -- there's a  
18 compounding component of Nephron, and then there's  
19 another, a manufacturer?

20 A. Yes.

21 Q. You said earlier that they only do  
22 injectables, are you talking about the compounding,  
23 Nephron compounding?

24 A. Yes. The injectables are the compounding  
25 side, that's our 503B division, and then we have a

1 manufacturing division which is mostly inhalation  
2 products.

3           However, we have filed for a few ANDAs,  
4 so we are now becoming a generic manufacturer for  
5 some injectables.

6 Q.       So when you talk about -- when you said the  
7 compounding portion of Nephron, is that Nephron  
8 Sterile Compounding Center?

9 A.       Are you asking about exact business name?

10 Q.       Well, there's Nephron Pharmaceuticals  
11 Corporation, and then there's Nephron Pharmaceutical  
12 Corporation, doing business as Nephron Sterile  
13 Compounding Center.

14           Do you work with the sterile compounding  
15 center?

16 A.       I work with both, but primarily the sterile  
17 compounding, yes.

18 Q.       Okay. Are you familiar with Nephron Sterile  
19 Compounding Center?

20 A.       Yes.

21 Q.       Okay. And you work directly with them?

22 A.       Yes.

23 Q.       As part of your arrangement with the  
24 university?

25 A.       Yes.

1 Q. Okay. And what are the differences between  
2 the requirements for a 503A pharmacy and a 503B  
3 pharmacy?

4 And I know -- I'm sure there are varying  
5 degrees of complexity, and we don't have all day, but  
6 if you could just sort of give me a thumbnail sketch  
7 of the primary differences between a 503A and a 503B,  
8 that would be good in terms of --

9 A. Okay. So the 503A pharmacy follows USP 797  
10 guidance. Those are the minimum requirements to  
11 follow.

12 So the USP 797, that chapter basically  
13 describes for a practitioner how to prepare safe,  
14 sterile compounded products. So you need to follow  
15 that exactly as stated or better. If you can have  
16 your procedure better than what the 797 requires,  
17 better yet.

18 So the 503B compounding requires that you  
19 follow CGMP, and so CGMP is more focused on like a  
20 manufacturing type of a setting.

21 So there are a lot of additional tests  
22 that are required per CGMP than they have to do in  
23 the manufacturing setting to assure that our products  
24 are safe and effective for the patients. And so  
25 while --

1 Q. Why is that? Why is that?

2 A. That is because while the USP 797 typically  
3 requires -- you have a prescription and you are going  
4 to dispense it to the patient and the medication will  
5 be used in a relatively short time, it's assumed.  
6 You have a prescription that's patient specific and  
7 it's written to be used.

8 When we compound our products on the  
9 large scale in the outsourcing, what happens are  
10 these products are drugs that will be shipped to  
11 hospitals, and so it may be another week or two  
12 before they are used. And so because of that -- or  
13 maybe even longer. And so we have to assure that the  
14 packaging withstands the shipping.

15 So, like I said, there are multiple  
16 quality measures in place to make sure that the drug  
17 itself gets where it needs to get safely, that it  
18 does not degrade, that it has the potency -- when it  
19 gets to the patient, it has the potency that we  
20 promised it would, that we say it does, and that type  
21 of stuff. So it is a little more intricate.

22 And, of course, there are multiple  
23 precautions put in place in terms of 503B compounding  
24 to minimize the potential for -- potential, for  
25 example, of microbial contamination.

1           So while in a 503A environment you don't  
2 gown -- you don't gown much. Like, you can still  
3 have certain areas of skin exposed, for example.

4           Because 503B, again, the assumption is  
5 the beyond use date, which will be relatively short,  
6 and so there is not as much concern with  
7 contamination, because, hopefully, the drug will be  
8 dispensed soon.

9           When it comes to 503B, we compound and  
10 these medications will be sent and transported, and  
11 so the guidelines on how to manufacture are very  
12 stringent.

13 Q.       And that's because it can affect a lot more  
14 people too, right?

15 A.       Absolutely, yes. Absolutely, that's  
16 definitely. You know, I didn't mention that, but,  
17 yes, that's definitely a big concern as well.

18 Q.       So Nephron Compounding Center is under the  
19 503B requirements that are much stricter because they  
20 are producing large quantities of compounded  
21 medications that are going to be used in hospitals  
22 all over the country, right?

23 A.       Correct.

24           MS. LEONARD: Object to the form.

25       ///

1 BY MR. SUTHERLAND:

2 Q. You say in your CV that you oversee  
3 formulations and filling operations for Nephron; is  
4 that right?

5 A. So I collaborated the departments that do --  
6 I used to do more of that when I started. Now the  
7 scale is so large that I cannot oversee every single  
8 formulation and every single filling operation, but I  
9 do assist with that.

10 Q. Tell me -- so at Nephron, what -- tell me  
11 again how many days a week on average you are working  
12 at the company.

13 A. Again, it depends. It depends on -- it's  
14 week to week, depending on what goes on at the  
15 college, how many students I have on rotation with  
16 me.

17 Q. On average, how many days a month are you at  
18 Nephron?

19 A. So a month, I can't say. But a week, I would  
20 say at least three. Two to three is very common,  
21 sometimes more; three probably would be the least.

22 Q. All right. And when you are at Nephron, tell  
23 me what you are doing while you are there during the  
24 day.

25 A. Again, it really depends. Nephron is a very

1 unique site. We do -- I'm involved in a lot of  
2 different things, anything from product development,  
3 where I attend meetings where we discuss short-term  
4 plans, as in what are we making this week; looking at  
5 shortage lists and determining what are we going to  
6 be making moving forward.

7 I have to look at -- if we decide, let's  
8 say we are going to do a new product, and I will look  
9 at the formulation and we will discuss how to best  
10 prepare it, we do some trial batches.

11 If I go to meetings for the long-term  
12 planning, we are looking at potentially filing some  
13 ANDAs. So I'm involved in providing feedback on how  
14 we are going to proceed in terms of the new drug --  
15 Abbreviated New Drug Application plan, what is the  
16 next drug that we should focus on.

17 And we look at our market analysis. I  
18 even look at that. Then I look back at formulation,  
19 how it's used in clinical setting.

20 A lot of these products may have multiple  
21 strength, multiple different packaging  
22 configurations, so we typically don't want to make  
23 all of them. You have to focus on what would be --  
24 what would make the most sense in the facility and  
25 the workforce that we have, so I focus on that.

1                   Then I'm involved in currently we are  
2                   working on a cleaning validation revamp, so we  
3                   perform cleaning validation -- well, the cleaning  
4                   team performs cleaning validation of the system in  
5                   between the products, but I help with determining the  
6                   cleaning validation limits, and those are based on,  
7                   you know, literature. So a variety of projects.

8           Q.           Yeah. So is there -- there are injectables  
9                   being compounded at the compounding center, right?

10          A.           Yes.

11          Q.           In Columbia?

12          A.           Yes.

13          Q.           And are you ever in the compounding center  
14                   where they are compounding these injectables?

15          A.           I mean, the plant where I am is all together,  
16                   so I am at the center.

17          Q.           Are you ever in the place where they are  
18                   doing the compounding?

19          A.           As a matter of fact, I'm getting gown  
20                   certified next week so I can go back in. Gown  
21                   certification has to be every six months. So I get  
22                   gown certified and I take my students back in there,  
23                   and sometimes I'll go and look and see how things are  
24                   done.

25                   We had some questions, for example, about

1 the way that product was made, and so I would go in  
2 there and actually observe. I don't -- if you are  
3 asking if I compound myself; no.

4 Q. Do you observe the compounding being done?

5 A. I do sometimes; not daily, but I do.

6 Q. You said "not daily"?

7 A. Right.

8 Q. Yeah. Do you frequently observe the  
9 compounding?

10 A. What's considered frequently?

11 Q. Well, using your definition. Do you  
12 regularly observe compounding that's being done there  
13 when you are there?

14 A. I do, because I take my students, and so we  
15 will go and observe.

16 Q. And how do you do that? How do you observe?  
17 Is it like glass and you are, like, looking in where  
18 it's being done?

19 A. It depends. For example, once my students  
20 are gown certified, we go in to observe.

21 Q. Right.

22 A. Like before they get gown certified -- as in,  
23 I have my students starting very recently. And so  
24 they will be gown certified on Monday, so we'll all  
25 go and then we'll go in. So once they are gown

1 certified, they will be able to go in.

2 So maybe the first week of the month --  
3 before they get gown certified, we can't go in. So I  
4 might just show them -- like, I show them through the  
5 glass what happens, but we will go and do an  
6 in-person once they are able to.

7 Q. When was the last time you did any sterile  
8 compounding?

9 A. When was the last time I did sterile  
10 compounding, as in I compounded?

11 Q. Uh-huh.

12 A. That would be -- are you asking about now or  
13 any?

14 Q. Any.

15 A. I would say when I was teaching and I was  
16 still in the hospital, is when I did it. So that  
17 would be 20- -- whenever I was a hospital employee,  
18 so I would say sometime in 2017-2018. I do not  
19 remember exactly when, but it would be back then.  
20 When I was teaching the lab, I prepared a number of  
21 sterile compounds on a daily and weekly basis.

22 I would work in the hospital and I would  
23 come and demonstrate for students, I would prepare  
24 compounds, a great number of compounds, and even very  
25 complex ones.

1           As in, when I was teaching sterile  
2   compounding, we would make a TPN, total parenteral  
3   nutrition product -- I'm sorry, when I was  
4   compounding with my students and they were preparing  
5   things like TPN, total parenteral nutrition, those  
6   are extremely complex preparations, and I would -- I  
7   would prepare those.

8           I prepared hazardous drug compounds using  
9   closed system transfer devices. The CSTDs, that's a  
10   relatively complex procedure. So I would say, while  
11   I was teaching the lab, I was compounding.

12           Now as an outsourcing pharmacist, I don't  
13   compound directly. And that's because in the  
14   outsourcing environment, per CGMP, I would have to do  
15   a special certification, and so I don't do that.

16           Plus, the way that we compound at  
17   Nephron, it's really large scale, so it's really not  
18   so much hands-on manipulation. You know, we call it  
19   compounding, but really it comes down to really  
20   mixing and preparing the drugs.

21           And those are done on a large scale as  
22   in, you know, you have bigger bags and you have --  
23   you know, you add -- you weigh out APIs and you add  
24   the powders in, and so it's done on a different scale  
25   now.

1                   So I observe these. I help with  
2 providing feedback on those, but I don't practice. I  
3 am not compounding with my hands, formulating it.

4 Q.           I understand. You help people -- you help  
5 Nephron and its employees comply with the regulatory  
6 requirements, USP and CGMP, and others?

7 A.           Yes.

8 Q.           And when you said a bunch of stuff about,  
9 when you were in the lab, about compounding you did.  
10 When you talked about compounding with the students,  
11 are you talking about at the school?

12 A.           Yes. So you have --

13 Q.           What happens to those compounds? What are  
14 they used for?

15 A.           So these are not used. They are prepared  
16 exactly as a normal compound would be, because the  
17 lab that we have at the college, it is perfectly ISO  
18 Class 5, ISO Class 7 compliant.

19                   So our facilities at the college, I  
20 really take pride in that because that's really  
21 something very unique about our College of Pharmacy.  
22 We have sterile compounding facilities that are up to  
23 all of the regulations. Simply, you could use the  
24 products that we make in patients. They are  
25 sterile --

1 Q. So what do you do with them?

2 A. So we don't use them. They are really  
3 strictly just to -- you know, we compound them and  
4 then we dispose of them.

5 Q. And after you compound them, do you do  
6 anything with them?

7 MS. LEONARD: Object to the form.

8 THE WITNESS: What would we do with them?  
9 I'm not sure I understand.

10 BY MR. SUTHERLAND:

11 Q. Do you send them off for testing or do  
12 you-all test them in the school?

13 A. Oh, good question. So, yes, in some -- yes,  
14 depending on what product we make, we do have  
15 exercises where we actually test the accuracy of the  
16 preparation. So, yes, there are times when we do  
17 test them.

18 Q. Do you always do potency and sterility tests  
19 on the preparations that you do in the school?

20 A. Not necessarily, because there is no need for  
21 that. These are not going to be used. I mean, if it  
22 was used in a patient, in a person, that would be  
23 different.

24 Q. Okay. Let me ask you this. Do you have any  
25 recognized specialty in your profession?

1 A. I'm not sure I understand what you are  
2 asking.

3 Q. Do you have any recognized specialty as a  
4 pharmacist?

5 A. You mean if I'm board certified?

6 Q. Well, doctors have specialties, I'm just  
7 asking you if you have any particular specialty in  
8 the practice of pharmacy.

9 A. I would say sterile compounding.

10 Q. Okay. And who recognizes that as a specialty  
11 that you have?

12 Is there a certification or from an  
13 organization that would recognize you as having a  
14 specialty in -- I'm sorry, as having a specialty in  
15 compounding?

16 A. So there is -- recently there was an approval  
17 for the board certification in sterile compounding,  
18 and I'm working on that, but I have not had time yet  
19 to take the exam.

20 So I will be pursuing that, as well as  
21 I'm pursuing a RAC certification, which is like a  
22 Regulatory Affairs certificate, as well.

23 Q. Let me ask you this. Can you identify for me  
24 the sources of your knowledge in the area of  
25 compounding, sterile compounding?

1                   Where does your knowledge of sterile  
2                   compounding come from?

3           A.       So I have practiced -- you know, when I was a  
4           student intern at Lexington Medical Center, I  
5           performed a lot of sterile compounding.

6                   I have performed sterile compounding  
7           while teaching the courses, the lab courses. I  
8           worked in a hospital where I performed sterile  
9           compounding.

10                   I have done a lot of research on sterile  
11           compounding. I have taken certification, not --  
12           these are courses, not -- continuing education.  
13           That's what I meant to say. Continuing education  
14           courses that deal with sterile compounding.

15                   I went to the critical point training in  
16           Colorado that offers like a three-day or five-day,  
17           whatever, boot camp in sterile compounding, so I have  
18           done that. So that has been my primary focus in my  
19           practice.

20           Q.       In terms of actually doing sterile  
21           compounding, would you say your experience as a  
22           student intern and then your work at the Palmetto  
23           Health Richland Hospital Pharmacy is the primary sort  
24           of actual sterile compounding experience you have  
25           had?

1 A. That as well as teaching. I mean, I prepare  
2 sterile compounds with my students in the lab. And,  
3 you know, we do those, we use real medications in the  
4 lab course. We use all of the -- you know, we follow  
5 all of the procedures as you would, you know, in the  
6 real world.

7 Q. But you don't use those on patients, though,  
8 right?

9 A. Right, but that doesn't matter. They are  
10 still prepared that they could be used. They are  
11 prepared according to all of the regulations.

12 Q. What would they have to be -- what would have  
13 to be done to them before they could be used on a  
14 patient?

15 A. Nothing. I mean, they are --

16 Q. Somebody have to -- would somebody have to,  
17 like, test them to make sure that they were -- that  
18 they met all of the USP requirements in terms of  
19 potency and sterility and all of that?

20 A. Well, it depends. It depends on how are they  
21 going to be dispensed and where are they going to be  
22 dispensed to and all of that.

23 Q. You listed in your report that you have  
24 worked as an expert in -- in the last four years you  
25 have provided testimony at trial or by deposition in

1 three cases; is that correct?

2 A. I'll have to double-check. That sounds  
3 right.

4 MR. SUTHERLAND: Rob, can you pull up  
5 Exhibit 2, the top of page 2?

6 THE WITNESS: Yes, I see them.

7 BY MR. SUTHERLAND:

8 Q. In the matter of the Federal Bureau of  
9 Prisons' execution protocol, Swearingen versus Davis  
10 and Pizzuto versus Tewalt, a case in Texas and one in  
11 Idaho, are those the only three cases that you have  
12 provided testimony in in the last four years?

13 A. I believe so. So the first one there was  
14 a -- I think there was just one testimony. Looking  
15 at this, I think I consulted with the attorneys and I  
16 provided them all of the information, and this is  
17 what they summarized.

18 THE WITNESS: Is that right, Lynne?

19 I know I provided a list of the cases.  
20 In that first one, I think there were a couple  
21 different expert opinions, if -- I believe that I  
22 did, but they summarized them as one because it was  
23 the same case.

24 MS. LEONARD: Yes. I'll interject. I  
25 think that some of the issue here might be clarifying

1 testimony versus expert report.

2 MR. SUTHERLAND: I understand.

3 MS. LEONARD: Which we all should have  
4 done, and that's our mistake on the lawyers' end.  
5 But for purposes of the questioning, I think there  
6 might be a little confusion there.

7 MR. SUTHERLAND: I got you.

8 BY MR. SUTHERLAND:

9 Q. Dr. Almgren, have you provided an expert  
10 opinion in the form of expert reports in any other  
11 cases in the last three years?

12 A. I think this is what -- like I said, I think  
13 the first one. There may have been a couple, but it  
14 was under the same umbrella, so --

15 Q. I understand.

16 A. Yes. So that's all, I believe.

17 Q. All right. And all of those cases involve  
18 the lethal injection protocol litigation; is that  
19 right?

20 A. Correct.

21 Q. And your consultation in all of those cases  
22 has been with attorneys for the inmate; is that  
23 right?

24 A. Yes.

25 Q. Have you ever consulted with the state in

1 regard to any lethal injection protocol?

2 A. No.

3 Q. Other than this case, have you ever consulted  
4 with any state or with any -- I'm sorry, with any  
5 attorneys involving a protocol other than  
6 pentobarbital?

7 A. No, it has been so far pentobarbital.

8 Q. So this is the only case that you have  
9 consulted with any attorneys involving a protocol  
10 using the three drugs that we are talking about?

11 A. Correct.

12 MR. SUTHERLAND: Okay. So, Lynne, I'm  
13 about ready to move into the substance of the report.  
14 Do you want to break? Do a short break for lunch  
15 now -- I know it's 12:45 for you guys -- before I get  
16 into some pretty substantive matters. I'm glad to do  
17 it either way. I don't eat lunch.

18 MS. LEONARD: I don't care.

19 Dr. Almgren, is this a good time for you  
20 to take a lunch break?

21 THE WITNESS: I guess the question is how  
22 much more time are we going to need? Are we going to  
23 go for an hour or is it going to be another four  
24 hours?

25 MR. SUTHERLAND: It's going to be a

1 while.

2 THE WITNESS: Okay. So then I guess it's  
3 probably better if we do take a break so I can  
4 freshen up.

5 MR. SUTHERLAND: What would be good for  
6 you? How long would you like?

7 MS. LEONARD: Let's see here, so it's  
8 about 12:45.

9 MR. SUTHERLAND: About 1:30?

10 THE WITNESS: Yeah, that's perfect.

11 MR. SUTHERLAND: Is that okay, Lynne?

12 MS. LEONARD: That's fine with me.

13 MR. SUTHERLAND: 1:30 Eastern time, 12:30  
14 Central. Is that okay with everybody else? Is there  
15 anybody else that needs more time than that that's on  
16 here?

17 I'm specifically going to ask Rob  
18 Mitchell, because he's always hungry. Is 45 minutes  
19 long enough for you, Rob?

20 MR. MITCHELL: I'm punching the Jimmy  
21 John's app as we speak.

22 MR. SUTHERLAND: Let's plan to be back at  
23 12:30 Central, 1:30 Eastern.

24 MS. LEONARD: Okay.

25 (Lunch break.)

1 BY MR. SUTHERLAND:

2 Q. Dr. Almgren, thanks for coming back. We  
3 didn't scare you away yet?

4 A. No, it's fine.

5 Q. When we took the break earlier, did you talk  
6 to anybody?

7 A. No.

8 Q. Nobody communicated with you about the case?

9 A. No, no.

10 Q. Okay. When were you -- can you tell me when  
11 you were retained to provide expert opinion in the  
12 case?

13 A. When as in what date was I retained?

14 Q. I'm not asking you for the specific day, but  
15 just generally. Can you tell me approximately when  
16 it was? Or if you know the date, you can tell me.

17 A. I do not know, I would have to look back. I  
18 have a very busy schedule and a lot of things  
19 happening in my schedule. I would have to look back  
20 and see when I signed the contract.

21 Q. Was it in 2021?

22 A. Yes, I think so.

23 Q. Last year?

24 A. Yes.

25 Q. Was it in the spring, summer, fall?

1 A. Honestly, I can't even guess, because I don't  
2 remember.

3 Q. Okay. Was it definitely last year, though?

4 A. Oh, boy, I'll have to -- I can look at the  
5 contract and tell you the exact date. Honestly, I do  
6 not recall.

7 Q. All right. And who contacted you about the  
8 case, about providing expert help in the case?

9 A. I also do not remember. Again, I don't  
10 remember a date. I'm not sure. I can look at my  
11 email and determine that.

12 MR. SUTHERLAND: Rob, could you pull up  
13 Exhibit 3 -- I'm sorry, Exhibit 2. That would be  
14 Dr. Almgren's initial report from November. And if  
15 you could go to page 2, Materials Relied Upon.

16 BY MR. SUTHERLAND:

17 Q. Dr. Almgren, under numerical paragraph 5, do  
18 you see that there on page 2?

19 A. Yes.

20 Q. You say, "The attorneys who represent  
21 death-sentenced prisoner Terry Lynn King asked me to  
22 submit an expert medical and scientific opinion based  
23 on the documentation provided to me about whether the  
24 use of the three-drug protocol, and in particular  
25 compounded medications, can cause a risk of harm and

1 unnecessary suffering." Do you see that?

2 A. Yes.

3 Q. Is that the question you were asked to  
4 answer?

5 A. Yes.

6 Q. Whether the three-drug protocol, and in  
7 particular compounded medications, can cause a risk  
8 of harm and unnecessary suffering?

9 A. That's correct.

10 Q. And were there any other questions other than  
11 that one question that you were asked to answer?

12 A. Not that I know of.

13 Q. Okay. And when you say the three-drug  
14 protocol, you are talking about Tennessee's  
15 three-drug protocol?

16 A. Yes.

17 Q. I want to start and talk to you about your  
18 initial report, to start with. And starting at  
19 page 3, "Standards governing." It's actually Roman  
20 Numeral III on page 3.

21 "Standards governing the preparation of  
22 compounded medications and medication storage and  
23 handling." Do you see that?

24 A. Let me see here. Yes.

25 Q. Okay.

1 A. I pulled it up on my screen as well.

2 Q. Sure. So just make sure that when you are  
3 talking about -- when I'm talking about your report,  
4 I'm talking about what's on my screen; just make sure  
5 that we are talking about what's on my screen as  
6 well, okay?

7 A. Yes.

8 Q. It should be the same, but I just want to  
9 make sure I'm asking you questions about what's on my  
10 screen, not what's on yours.

11 A. Okay.

12 MS. LEONARD: Just for the record, they  
13 should be the same, right?

14 MR. SUTHERLAND: Yeah, they should be the  
15 same.

16 MS. LEONARD: Yeah.

17 MR. SUTHERLAND: For the testimony -- the  
18 record should be clear that I'm asking questions  
19 about this. If she sees that there's a difference  
20 than what's on the screen, she can let me know.

21 I'm representing, Dr. Almgren, that this  
22 is a copy of the report that was provided to me as  
23 your report. And so when you -- as I understand it,  
24 you looked through it earlier and this report  
25 matches -- is your report. So I just want to make

1       sure that we are talking about the same one, okay?

2               MS. LEONARD: Yeah. I think,  
3       Dr. Almgren, did you pull up the report that was  
4       emailed to you?

5               THE WITNESS: Yes, I did.

6               MS. LEONARD: When you say that you are  
7       looking at the report, that's what you are talking  
8       about, is the one that came out of the email?

9               THE WITNESS: Yes, that's correct.

10              MS. LEONARD: Scott, there shouldn't be  
11       any differences between what you are looking at and  
12       looking at the email.

13              MR. SUTHERLAND: Yeah.

14              MS. LEONARD: Just so we have that all  
15       clear.

16       BY MR. SUTHERLAND:

17       Q.       So, Dr. Almgren, let me start with this and  
18       ask you. What is the United States Pharmacopeia?

19       A.       USP itself; so that's kind of a big question,  
20       because it's really a set of guidance or guidelines  
21       that range from anywhere about, you know, talking  
22       about drug quality, to certain procedures, quality  
23       measures. You know, it has a list of procedures that  
24       you are to follow, you know, when you perform quality  
25       analyses.

1           It has a list of monographs that  
2       basically, you know, delineate the quality standards  
3       for different drugs. So, you know, it's a really big  
4       question. When you say: What is USP, that's kind of  
5       like me asking you what is U.S. law.

6           You know, it's a collection of many  
7       different things, and that's what USP is.

8       Q.       Tell me if you'd agree with this: A  
9       compendium of quality requirements, quality  
10      specifications, practices and guidelines to achieve  
11      the highest pharmaceutical quality for pharmacy  
12      practice as well as the pharmaceutical industry. Is  
13      that a fair definition?

14      A.       A fair definition, yes.

15      Q.       Okay. I'd next like to ask you, what is  
16      USP 797?

17      A.       So that is a chapter from the compendium. So  
18      the compendium has a number of chapters. And the  
19      chapters zero to 1,000 are required, you must follow  
20      those. The ones above 1,000 are guidelines.

21           And a lot of times they are really more  
22      of explanations, like a follow-up, more of an  
23      explanation for what the chapters stand for.

24           So the Chapter 797 is a requirement, you  
25      have to follow that one because it's below 1000. And

1 that chapter basically describes what are the  
2 appropriate practices for sterile compounding.

3 MR. SUTHERLAND: Rob, can you put up  
4 Exhibit 5? We'll go ahead and send that to  
5 Ms. Leonard and Dr. Almgren.

6 BY MR. SUTHERLAND:

7 Q. I think, Dr. Almgren -- well, we'll wait  
8 until he pulls it up here. It should be a PDF of  
9 USP 797.

10 So Mr. Mitchell has got up there what  
11 purports to be the most recent version of the  
12 USP 797. And we are sending it to you, and if you  
13 could look at it and tell me if you agree with that.

14 MS. LEONARD: It just came through to me,  
15 so I just forwarded it to Dr. Almgren.

16 BY MR. SUTHERLAND:

17 Q. Are you familiar with USP 797, Dr. Almgren?

18 A. I am.

19 Q. Have you seen this particular version of it?

20 A. I apologize, the dog.

21 Yes, I have seen -- I have seen this  
22 version. This is the most recent one.

23 Q. Okay. Did you send a version like this to  
24 your counsel to provide to us?

25 A. Yes.

1 Q. Okay. If I told you that this was the  
2 version, I believe, that they provided to us, do you  
3 have any reason to disagree with that?

4 A. No.

5 Q. Okay. Let me ask you this. From a  
6 regulatory standpoint, who is regulated by USP 797?

7 A. So this is a good interesting question that  
8 my students often ask. So the USP 797, the  
9 compendium itself is written by experts in a field.  
10 And so those are folks that work in and are very  
11 familiar with that particular -- whatever expertise  
12 is addressed in a specific chapter.

13 So the USP itself is nongovernmental type  
14 of organization, but the USP itself is -- the  
15 guidelines themselves are enforced by FDA.

16 Q. All right. And so they are enforced by FDA.  
17 But who is regulated by the -- I want to know who the  
18 regulated parties that FDA would enforce USP 797  
19 against would be.

20 Who would those people be?

21 A. I see. So, for example, drug industry, you  
22 know, the manufacturers of the drugs, they follow the  
23 USP -- not 797; USP in general.

24 We are talking about USP, right, not 797?

25 Are we talking about 797 specifically?

1 Q. I'm talking about 797.

2 A. Okay, specifically. So USP 797, obviously,  
3 the FDA enforces, requires. And so these are the  
4 best practices for the compounding.

5 So depending on how -- the different  
6 boards of pharmacy set up different Pharmacy Practice  
7 Acts, a lot of the states in the United States have  
8 accepted USP Chapter 797 as their quality standard.

9 Q. Right.

10 A. So if that happens, then that guideline is  
11 acceptable and it's seen forceable by the Board of  
12 Pharmacy of the state that had accepted this guidance  
13 as their sterile compounding guidance.

14 Q. Who is --

15 A. Also a lot --

16 Q. Let me finish my question.

17 Who is it enforceable against?

18 A. The pharmacies that compound according to  
19 503A.

20 Q. Okay. Who else?

21 A. I mean, that's whoever prepares sterile  
22 preparations.

23 Q. So USP 797 is enforceable against the  
24 pharmacy that prepares it?

25 A. Right.

1 Q. Is there anybody else that it's enforceable  
2 against?

3 A. I'm not sure I understand the question. As  
4 in public? I don't know who you are asking.

5 Q. I'm asking you if this applies -- USP 797  
6 practices are enforceable by the FDA. Who does the  
7 FDA enforce it against? And you just said  
8 pharmacies, compounding pharmacies.

9 Is there anyone else?

10 A. So, as I said, if the Board of Pharmacy in a  
11 state accepts USP Chapter 797 as a part of their  
12 Pharmacy Practice Act.

13 Q. Yes.

14 A. And the Board of Pharmacy will enforce, but,  
15 again, it's the pharmacies, and it can be a  
16 compounding pharmacy. It can be a hospital pharmacy.  
17 All of these pharmacies will have to follow the USP  
18 Chapter 797.

19 As a matter of fact, even in the states  
20 where 797 is not accepted as a standard, which there  
21 are just a very few states at this point left that  
22 have not accepted 797 in its entirety, what happens  
23 in those states, typically the pharmacies will accept  
24 the 797 as standards, because the Center for Medicare  
25 and Medicaid Services requires that accreditation

1 bodies audit pharmacies. And the pharmacies must  
2 follow 797 in order to get the accreditation in order  
3 to get reimbursement from CMS.

4 Q. I understand. Once it leaves the compounding  
5 pharmacy, does 797 apply to anyone else?

6 A. Well, yes, because you need to make sure  
7 that, when the drug is handled, that whether it is a  
8 nurse that, maybe, applies the medication, or maybe a  
9 doctor, whoever handles the medicine, the medication  
10 should be continued to be handled according to 797.

11 Q. I understand it should be handled.

12 My question is, is it -- does the FDA  
13 regulate 797 against anyone once it leaves the  
14 compounding pharmacist?

15 A. I'm not sure I quite follow your line of  
16 question.

17 Q. Okay. So --

18 A. How would FDA -- just, yeah, explain that a  
19 little more. I'm sorry.

20 Q. Okay. Well, if a compounded medication is  
21 given to a nurse to administer, is the FDA going to  
22 regulate how the nurse administers 797, or how the  
23 nurse administers the compounded medication?

24 A. So, technically, yes. If you look and you  
25 would like to reference the chapter, we can look at

1 the chapter itself and I can reference, the chapter  
2 covers all of the -- not just the preparation, but  
3 also handling.

4 And so technically -- to give you an  
5 example, to really explain in the real world what  
6 happens, so let's say in a hospital, if we have an  
7 audit and we need to show that we follow 797, if I  
8 prepare sterile compounded medication and I send it  
9 to the floor, the folks who are performing the audit  
10 will actually follow the records and follow -- if  
11 it's happening in the real time where I just  
12 compounded, it would actually follow the medication  
13 to see that it is applied according -- or they have  
14 an option to -- I'm not saying that they necessarily  
15 would -- but an option to go to the floor and see how  
16 it is applied to complete the audit.

17 Q. So does the FDA cite -- are you aware of the  
18 FDA citing healthcare professionals who actually  
19 administer sterile compounds for not following 797?

20 A. I am not aware. But the audits -- so  
21 whenever there's an audit, the auditors in the past  
22 have cited healthcare facilities for improper  
23 handling of sterile compounds, not the FDA itself.

24 If that's your question, then not the  
25 FDA, but the other regulatory bodies that would make

1       sure that the USP Chapter 797 is followed in a  
2       facility.

3       Q.       Who else -- who else would -- you say  
4       auditors. You are not talking -- you said that  
5       wouldn't be the FDA?

6       A.       So, no, that doesn't necessarily have to be  
7       the FDA. It can be an accreditation body that comes  
8       to accredit on behalf of CMS.

9       Q.       Okay. What about common carriers, can they  
10      be regulated? Are they regulated by the FDA for 797  
11      requirements?

12     A.       So there are, I know -- I'm trying to  
13      remember what the exact guidance is. And, honestly,  
14      I can't answer this with 100 percent certainty, so I  
15      do not know.

16     Q.       What about patients, do compounding  
17      pharmacies once a -- let's say in a 503A pharmacy, a  
18      patient has a prescription and picks up their  
19      prescription and it's, say, a high-risk sterile  
20      compound. Does the FDA regulate the patient's use of  
21      the compound?

22     A.       So this is a little bit ambiguous, because I  
23      don't have enough details to really answer,  
24      because -- technically, no.

25               I mean, you don't -- the FDA is not going

1 to come knocking on your door to see what you are  
2 doing with your compound.

3 But then why would you have aseptically  
4 prepared medication given to the patient, like, what,  
5 are they administering it themselves at home?

6 Q. Sure.

7 A. I guess I can't quite --

8 Q. Yes.

9 A. I'm trying to understand the question.

10 Q. Do compounding pharmacists dispense high-risk  
11 sterile compounds to patients that store, for  
12 example, refrigerated products for  
13 self-administration?

14 A. I mean, that can happen, yes. You can  
15 definitely, you know, have patients who have  
16 medication at home that they give themselves,  
17 sterile, yes.

18 Q. How does -- how does the compounding pharmacy  
19 know or the FDA know whether or not the requirements  
20 of the USP 797 are followed once it leaves the  
21 pharmacy?

22 A. So you provide the storage conditions for the  
23 patient. So if I work in, let's say, a home-infusion  
24 pharmacy and I prepare all total parenteral nutrition  
25 product that I dispense to a patient, I will provide

1 under the Storage Conditions: You must refrigerate  
2 this, keep it in a temperature span between this and  
3 this.

4 If it gets outside of the temperature,  
5 please do not use the product, because we cannot  
6 guarantee that the product will be pharmaceutically  
7 active, that it will be, you know, working as it's  
8 supposed to.

9 Q. So back to my question about who is  
10 regulated. Is USP 797 -- can the FDA cite anyone  
11 that's a non-healthcare professional for not  
12 following USP 797?

13 A. Would that include like -- like patients?

14 Q. Any non-healthcare outside the healthcare  
15 setting, outside of a hospital, outside of --

16 A. No. I don't think FDA -- if you are asking  
17 me if FDA would cite them, I don't think FDA would.

18 Q. It doesn't apply; does it?

19 A. Right.

20 Q. In other words, people outside the  
21 healthcare setting in which compounded preparations  
22 are being administered aren't covered by USP 797?

23 A. Well, the medications are covered by 797.

24 Q. Sure.

25 A. You know, you need to follow the guidance in

1 order to maintain integrity of the product.

2 Q. I understand.

3 A. So, yes, they need to handle it according to  
4 797. But a person that, you know, handles the  
5 medication, you are not going to have the FDA come  
6 knock on your door to enforce the chapter, if that's  
7 what you are asking.

8 Q. Right. And the reason for that is that 797  
9 applies to -- the objective of 797 is to prevent --  
10 excuse me -- harm to patients in a clinical setting;  
11 isn't that right?

12 A. So the chapter in general applies, I believe,  
13 to anybody who handles the medication, you know, to  
14 give it to the patient.

15 Q. At the top where it says Introduction, it  
16 says, "The objective of this chapter is to describe  
17 conditions and practices to prevent harm, including  
18 death, to patients that could result from" the  
19 following.

20 It applies to the healthcare setting to  
21 prevent harm to patients; does it not?

22 A. Right.

23 Q. Okay. Does it apply in the lethal injection  
24 setting?

25 A. Absolutely.

1 Q. Are non-healthcare people in corrections  
2 covered by USP 797?

3 A. They are handling a sterile preparation.

4 Q. I'm asking you if USP 797 covers that.

5 A. I think that's a trick question, because they  
6 should be healthcare professionals that handle  
7 medication.

8 You would not have your pool guy give you  
9 an IV, so a person who handles the medications should  
10 be a healthcare professional.

11 Q. No. My question is, the purpose -- the  
12 objective of USP 797 -- you correct me if I'm  
13 wrong -- is to protect patients in a clinical  
14 setting; would you agree with that?

15 A. I would say it's to protect patients. I'm  
16 not -- the clinical setting, it's a wide definition,  
17 because you can be at home receiving an infusion,  
18 which by some definition may not be considered a  
19 clinical setting because you can say it's my living  
20 room, but if I'm receiving an IV at home, something  
21 like a total parenteral nutrition product, you know,  
22 it's still a procedure, medical procedure.

23 Q. Yeah. Actually, let me read the words at the  
24 top, the first sentence. "The objective of this  
25 chapter is to describe conditions and practices to

1 prevent harm, including death, to patients."

2 A. Uh-huh.

3 Q. So it's designed to protect patients from  
4 harm and death, right?

5 MS. LEONARD: Objection, asked and  
6 answered.

7 BY MR. SUTHERLAND:

8 Q. You can answer the question.

9 A. I mean, yes. That's what it states.

10 Q. Okay. Let me ask you this. How does  
11 enforcement of USP 797 work?

12 MS. LEONARD: Objection.

13 BY MR. SUTHERLAND:

14 Q. In your experience, how does the FDA enforce  
15 USP 797, or state pharmacy officials?

16 A. Typically, they perform audits. That's how  
17 it's enforced.

18 Q. Who do they audit?

19 A. They audit, typically, the pharmacy or  
20 healthcare setting where the medications are used,  
21 compounded.

22 Q. And if they don't -- if the pharmacy or the  
23 healthcare setting in which they are used doesn't  
24 follow them, what happens, or if they are inspected  
25 and there's an inspection and they find issues, what

1 happens?

2 A. So it really depends on the severity of the  
3 issues, because if it's something minor, you know,  
4 then you would just get cited and you need to make  
5 corrections. You may have to pay fines if it's  
6 something more serious.

7 And if it's something extremely serious,  
8 then they can shut you down. They can close the  
9 pharmacy.

10 Q. How does a regulated party get cited?

11 A. So basically they will write you a citation  
12 as in: This is -- we audited your facility. And  
13 these are the discrepancies that we found, and you  
14 get a citation. You know, it will list what are the  
15 issues that they had come across.

16 And, as I said, depending on severity, it  
17 might be a fine, may be more serious.

18 Q. Is that also called a Form 483?

19 A. So 483 is really for the manufacturer and for  
20 503B pharmacies; that's where you really see it the  
21 most. But, yes, 483 is a type of a report.

22 Q. All right. Is there a certain citation that  
23 is used for 503A?

24 A. So a lot of times the Board of Pharmacy will  
25 have their own forms that they use. Again, it

1 depends on the severity. It depends on, you know,  
2 what type of violation is going on. But, typically,  
3 they will have their own forms that they complete.

4 Q. I want to refer you to --

5 MR. SUTHERLAND: Rob, I want to go back  
6 to Exhibit 2, page 4, numerical paragraph 11.

7 BY MR. SUTHERLAND:

8 Q. Dr. Almgren, you say that: Compounding  
9 pharmacists should be familiar with USP 797  
10 guidelines in order to prepare safe and effective  
11 sterile compounded products. If USP 797 guidance is  
12 not followed, it can lead to medication  
13 contamination, which will cause patient harm and  
14 unpredictable effects. Is that right?

15 A. Yes.

16 Q. And I guess my question to you is, don't  
17 you -- you say a compounding pharmacist should be  
18 familiar, but how would you become a compounding  
19 pharmacist without being familiar with USP 797?

20 A. It depends on your training. You know,  
21 USP 797 has not been around forever. There are  
22 pharmacists that I work with that have not read USP  
23 Chapter 797 because, at the time when they graduated,  
24 USP was not around. And so, you know, the chapter  
25 was not a requirement of their education.

1           Also, the schools of pharmacy in general,  
2     you know, have different levels of emphasis on  
3     sterile compounding. There are some programs that  
4     emphasize sterile compounding. There are others who  
5     really don't, and you just get kind of a  
6     surface-level look. So it really depends.

7           You know, there are pharmacists who, for  
8     example, in retail, who maybe compound very  
9     occasionally sterile preparations. They mostly  
10    dispense.

11           So it really depends on your level of  
12    training and expertise and when you graduated, how  
13    much of the continuing education you have done in  
14    this realm. So there are a lot of factors. Not  
15    everybody is expert or even familiar with 797,  
16    really.

17    Q.       So if you are applying for a license to  
18    compound, say, in the state of Tennessee in the last  
19    five years, which in Tennessee requires USP -- has  
20    adopted USP requirements, wouldn't you have to  
21    demonstrate some degree of competency in order to get  
22    licensed to compound?

23    A.       You don't necessarily have to. I know I  
24    practiced in South Carolina, and in South Carolina  
25    there are really no specific requirements.

1           You apply for, you know, a permit for a  
2       compounding pharmacy, and you show -- the key here is  
3       to show you have the equipment that's needed. But in  
4       terms of specific training, a lot of states do not  
5       have the specific requirements.

6           The state of Massachusetts does after the  
7       New England Compounding Center issues. But there are  
8       still a lot of states that do not have specific  
9       requirements that, you know, require pharmacists who  
10      are compounding to have any special training.

11      Q.       In your experience, the pharmacists that you  
12      have dealt with at Rite Aid or in the Richland  
13      Hospital, are those pharmacists -- were those  
14      pharmacists familiar with USP 797?

15      A.       The experience varied greatly. So there are  
16      some who have experience, and there are some who have  
17      not.

18           As a matter of fact, I teach continuing  
19      education courses, so I actually teach sterile  
20      compounding to other pharmacists. And typically the  
21      pharmacists that come to take the continuing  
22      education courses have very little, if any, exposure  
23      to 797.

24      Q.       You say it will cause patient harm. If USP  
25      Chapter 797 guidance is not followed, it can lead to

1 medication contamination that will cause patient  
2 harm. It's actually "may cause harm"; is it not?

3 Not every failure to follow USP 797  
4 results in harm to a patient; does it? Or a person,  
5 I should say.

6 A. Yeah. I guess if you want to discuss whether  
7 will or could or can are important, then I guess you  
8 could say that maybe there could be a different verb  
9 used.

10 But, in general, it would be very  
11 concerning to have medication that's not compounded  
12 according to 797 to be applied. I wouldn't want that  
13 personally.

14 Q. My question to you is, just everything that  
15 doesn't -- every technical deficiency in following  
16 USP 797 does not result in harm to people?

17 Are you saying that every time you don't  
18 follow everything in USP 797, it results in harm to a  
19 person?

20 A. No. No.

21 Q. Okay.

22 A. What I was saying -- I think you are  
23 misunderstanding the sentence, because the sentence  
24 says: If USP Chapter 797 guidance is not followed,  
25 it can lead to medication contamination, which will

1       cause patient harm and unpredictable drug effects.

2               So I think you are taking this out of  
3       context, because I'm not saying that every  
4       contamination will cause, but it can lead to  
5       contamination and the contamination will cause.

6               I mean, if you have a contaminated drug,  
7       there's a very good chance that there will be some  
8       type of an issue.

9       Q.       So let's go back. Does every technical  
10      deficiency in following USP 797 result in harm to  
11      persons?

12     A.       It may.

13               MS. LEONARD: Asked and answered.

14               THE WITNESS: I don't have statistical  
15      data to state clearly. My assumption is I don't  
16      know.

17     BY MR. SUTHERLAND:

18     Q.       Well, are you saying that every technical --  
19      every technical requirement of USP that is not  
20      followed in 797 may result in harm to a person?

21     A.       So what I'm saying is it really depends on  
22      the technical deficiency.

23     Q.       That's what I'm asking you, all of them.

24               If you don't follow everything in USP 797  
25      to the law -- to the letter, will that always result

1 in patients or persons being harmed?

2 MS. LEONARD: Same objection.

3 BY MR. SUTHERLAND:

4 Q. You can answer.

5 A. There is a good potential, but I can't -- I  
6 don't know.

7 Q. It would depend on the issue and the  
8 circumstances, wouldn't it?

9 A. Exactly.

10 Q. For example, in the lethal injection context,  
11 the object of administering compounded drugs in this  
12 case is death.

13 So depending on the specific issues  
14 involved, it could result in no issue at all?

15 MS. LEONARD: Is that a question?

16 MR. SUTHERLAND: It is a question.

17 THE WITNESS: What's the question?

18 BY MR. SUTHERLAND:

19 Q. I'll give it more -- I'll give it more  
20 specific context here.

21 How long would it take for a contaminated  
22 drug to cause harm to a patient? How long would you  
23 need?

24 A. I don't understand the question. It depends  
25 on the drug. It depends on contamination.

1 Q. Let's say potassium chloride. Are you  
2 familiar with potassium chloride?

3 A. Yes.

4 Q. Okay. If potassium chloride was  
5 contaminated, say, with an endotoxin of some type,  
6 how long would it take for a person who is  
7 administered potassium chloride to be harmed by the  
8 contamination?

9 A. I don't know.

10 Q. You don't know? Would it be minutes?

11 A. I don't know. I think it depends, because we  
12 are talking about endotoxin contamination.

13 Are there particulates in there? Is it  
14 just microbiological-type? You know --

15 Q. Do you not know -- do you not know the answer  
16 to the question, or are you --

17 A. I don't think there's enough information.  
18 But if you are asking about minutes, I don't know  
19 that answer. I have not -- I can research this, but  
20 I do not know.

21 Q. Yeah. Do you think that a person that was  
22 administered potassium chloride that was contaminated  
23 with -- you name the endotoxin, would be harmed  
24 within minutes?

25 A. I don't know the answer to that question,

1 because I don't know what type of endotoxin. I don't  
2 know what --

3 Q. I'm asking you about any endotoxin.

4 A. -- quantity.

5 Q. Any endotoxin.

6 MS. LEONARD: I'm sorry. Just because  
7 this has happened a few times, could you please let  
8 Dr. Almgren finish her answer before you ask another  
9 question?

10 MR. SUTHERLAND: Sure.

11 THE WITNESS: Like, what quantity? You  
12 know, at what rate was it given? I mean, there are a  
13 lot of questions that would --

14 BY MR. SUTHERLAND:

15 Q. Sure.

16 A. -- have to be answered.

17 Q. Yeah. We'll come back to a specific example  
18 in a minute.

19 MR. SUTHERLAND: Let's look at, if we  
20 could, Rob, Section 4, which starts on page 5.

21 BY MR. SUTHERLAND:

22 Q. Just Section 4 that starts with numerical  
23 paragraph 12, Dr. Almgren, says: Unqualified  
24 personnel perform tasks in the protocol that should  
25 be done by professionals with much more extensive

1 training and education in pharmacy related issues.

2 Do you see that?

3 A. Yes.

4 Q. And as I read through Section 4, the only  
5 people you mention are the drug procurer and the  
6 executioner; is that right?

7 A. Okay.

8 Q. Is that correct?

9 A. It does appear that way.

10 Q. Okay. You don't mention any others. So I'm  
11 asking, are these the two people you are talking  
12 about in this section?

13 A. So these are the two I read the depositions  
14 for, and I felt strongly that they were the most  
15 issues associated with their practices.

16 Q. Are there any other people that you do not  
17 note in this report?

18 A. No. These are the two that I selected were  
19 good examples of why I felt very unqualified  
20 personnel were performing tasks that they were not  
21 qualified to do.

22 Q. If you had other examples that you thought  
23 were significant, would you have put them in here?

24 A. Potentially, yes.

25 Q. But you haven't put any others in here?

1 A. Right.

2 Q. Numerical paragraph 12 says: The selection  
3 process for the extremely crucial positions of drug  
4 procurer and executioner is not adequate, authorizing  
5 team members who have insufficient medical training  
6 to handle lethal injection chemicals without really  
7 understanding the procedures. Do you see that?

8 A. Yes.

9 Q. And your concerns about this particular issue  
10 are in this section of your report, correct?

11 A. Correct.

12 Q. Are there any concerns that are not in this  
13 report?

14 A. No, these are valid concerns.

15 Q. Paragraph 13: The drug procurer lacks the  
16 training and professional qualifications necessary to  
17 understand how to properly store and handle LICs.

18 If you go to the last -- I won't talk  
19 about the middle of that paragraph, but the last  
20 sentence says: This is a highly specialized position  
21 that should be held by a person with in-depth  
22 training in the listed areas, such as a pharmacist.

23 A. Are you asking a question?

24 Q. I'm going to ask you a question.

25 Are you saying that the drug procurer

1       should be a pharmacist?

2       A.       It should be somebody who is qualified to  
3       handle the medications correctly.

4       Q.       Such as a pharmacist?

5       A.       Yes.

6       Q.       Isn't that what you said?

7       A.       Yes.

8       Q.       Could a pharmacist administer lethal  
9       injection chemicals professionally?

10      A.       No. We are not allowed to -- or, we are  
11      not -- it depends on your Pharmacy Practice Act, I  
12      guess, on the training. But, typically, no,  
13      pharmacists are only allowed to inject things like  
14      vaccines or IM injections.

15               Here I'm really referring to somebody who  
16      is storing and handling the medications, drug  
17      procurer, not somebody who is administering the  
18      medications.

19      Q.       Could a layperson be educated and trained to  
20      handle compounded sterile products?

21      A.       Potentially, yes, but they need to be trained  
22      and they need to, you know, have a set of standard  
23      operating procedures, some type of a manual that will  
24      be spelling out all of the responsibilities and all  
25      of the procedures that they should follow.

1 Q. So the answer is, yes, a layperson can be  
2 trained and educated to do this?

3 A. Potentially, yes. The pharmacist would be  
4 preferred, because as a pharmacist, we have a  
5 training to evaluate things.

6 You would almost need to have a  
7 consulting pharmacist who maybe would oversee the  
8 operations of this person so you could address  
9 things.

10 Let's say you have issues with the  
11 storage conditions. How would a layperson be able to  
12 determine that that was okay or not okay?

13 Is it okay to use the medication or not?  
14 How would a layperson know? A pharmacist would.

15 Q. You'd have to ask -- you'd have to ask --  
16 what if you asked a pharmacist?

17 What if you were -- if you were a  
18 layperson trained and you consulted with the  
19 pharmacist, would that be good?

20 A. It depends, because as we discussed earlier,  
21 not all pharmacists are really thoroughly trained in  
22 this realm, and so they may not have the right  
23 answer.

24 Q. What if a pharmacist is trained and familiar  
25 with USP 797, can a person be trained to perform

1 these tasks in consultation with a pharmacist?

2 A. Sure, you could have a consulting pharmacist  
3 there who would oversee this, yeah.

4 Q. And in paragraph 13 you say, in the second  
5 sentence: Additionally, the drug procurer does not  
6 understand the difference between reagent chemical  
7 and USP grade APIs, regulations surrounding the drug  
8 procurement of controlled substances, drug  
9 substitution process, and how to determine the  
10 amounts of drugs needed, or the importance of careful  
11 documentation and drug beyond use dating assignment.  
12 Do you see that?

13 A. Yes.

14 Q. And what are you basing that sentence on?

15 A. I base it on the deposition of the drug  
16 procurer. Throughout the deposition there are  
17 multiple times where he mentioned he was looking at  
18 other drugs, and it was apparent from the  
19 deposition -- and I would have to go back. And if  
20 needed, I'll be happy to. We can pull up the  
21 deposition and read through, and I can point out what  
22 areas concerned me in the sense that he -- I felt  
23 that he did not have the qualifications for this  
24 position.

25 Q. But you didn't cite to the deposition

1 anywhere?

2 I mean, you cite to the deposition at a  
3 number of places, but you haven't cited to the  
4 deposition in particular anywhere in regard to these  
5 statements, have you?

6 A. There were so many instances, they would  
7 probably -- I guess, like I said, we can go back and  
8 I'll be happy to do that.

9 Q. Did you cite the specific instances where  
10 these issues were -- that you raise?

11 MS. LEONARD: Objection, asked and  
12 answered.

13 BY MR. SUTHERLAND:

14 Q. You can answer the question.

15 You have four or five different comments  
16 here, but you haven't cited to a single place in the  
17 deposition; is that true?

18 A. Right. Well, yes, not in this statement.  
19 Right.

20 Q. In paragraph 14 you say: The drug procurer  
21 lacks attention to detail. For example, the drug  
22 procurer testified that he believed an entry  
23 regarding the size of the midazolam vial he made in  
24 the drug inventory log was not accurate; is that  
25 correct?

1 A. Right. Yes.

2 Q. Okay. Have you cited to any other examples  
3 where the drug procurer lacks attention to detail?

4 A. Are you asking me if I cited other --

5 Q. I'm asking you specific instances that you  
6 can tell me -- you say he lacks attention to detail.  
7 You cited one.

8 Do you have other specific items, and  
9 where are they?

10 A. I will be happy to go -- can we open the  
11 deposition, and I will point them out.

12 Q. Well, if we had much longer, we would do it.  
13 Unfortunately, we don't have enough time for you to  
14 go back and read the deposition.

15 Do you consider this to be a significant  
16 lack of attention to detail in the first sentence --  
17 or second sentence of paragraph 14?

18 A. Yes. I mean, it appears that -- you know,  
19 these are important. This is one of the most crucial  
20 information about a drug, is the size of the  
21 medication, the beyond use date.

22 Those are -- I mean, if you don't keep a  
23 proper record of that, those are -- that's important.  
24 The handling of the medication, that is his job, is  
25 to procure and maintain the medication.

1 I mean, I'm not sure what other  
2 responsibilities this person has, but if this person  
3 is a drug procurer and his responsibility is to  
4 maintain the records, the number one responsibility  
5 should be his number one concern, maintain accurate  
6 and correct records.

7 Q. My question for you is: Do you consider this  
8 lack of attention to detail to be a significant lack  
9 of attention to detail; yes or no?

10 A. Yes, this and there are many other examples  
11 throughout his testimony.

12 Q. Okay. You cited to this one and you don't  
13 cite to any others; is that correct?

14 A. Correct.

15 Q. If you thought they were significant, why  
16 didn't you cite to them and put them in the report?

17 A. Just it would be a lot of notes. I just kind  
18 of summarized it and pulled an example.

19 Q. Are there anymore significant lack of  
20 attention to detail that you think should be in here?

21 A. No, that's a good example.

22 Q. I'm asking you if there are -- if there are  
23 numerous examples of the drug procurer lacking  
24 attention to detail that you think material, don't  
25 you think they should be in here?

1 A. No. I just demonstrated as one example. I  
2 mean, it's just a general statement. Yes, we can go  
3 back and look at the testimony and I'll point out a  
4 handful of others.

5 I just felt that, you know, I'll show an  
6 example of how -- what are some of my concerns. And  
7 I felt that this one was -- you are asking if this  
8 one is a significant one, that is significant.

9 As I stated earlier, if you are a drug  
10 procurer maintaining the records, this is what your  
11 responsibility is, so shouldn't you maintain the  
12 records accurately?

13 Q. Paragraph 15 you start talking about the  
14 executioner, so that's all, as I read your report,  
15 that you have noted on the drug procurer; is that  
16 fair?

17 You don't think there are any others  
18 other than those two paragraphs, 13 and 14?

19 MS. LEONARD: Objection, form.

20 BY MR. SUTHERLAND:

21 Q. Are there any other paragraphs or information  
22 where you are discussing the drug procurer, to your  
23 knowledge?

24 A. I will have to look. I do not know off the  
25 bat. Let me take a look at the document.

1 Q. Paragraph 22.

2 A. We discussed this further in Section 6.

3 Q. I'm talking about Section 4.

4 A. So you are looking only for the answer in  
5 Section 4; I got you.

6 Q. This is where you say: Unqualified personnel  
7 perform tasks. And you talk about the drug procurer  
8 in two paragraphs.

9 And I'm asking you, are there are any  
10 other paragraphs in this section where you talk about  
11 the drug procurer?

12 A. No. I believe the rest are focused on the  
13 executioner.

14 Q. In paragraph 15 you say: The executioner  
15 should be assigned to a person with medical or  
16 pharmacy training.

17 What type of person are you talking  
18 about?

19 MS. LEONARD: Objection to the form.

20 THE WITNESS: So it would -- you know, a  
21 pharmacy technician or pharmacist would be more  
22 appropriate to prepare the medication, and to  
23 administer, probably a nurse or somebody on that  
24 level of training would be more appropriate.

25 ///

1 BY MR. SUTHERLAND:

2 Q. Could a nurse ethically administer lethal  
3 injection chemicals?

4 A. I don't know. Is that a question as in --

5 Q. Yeah, I'm asking you.

6 Could a nurse -- could you ethically  
7 administer lethal injection chemicals?

8 A. Me as a pharmacist?

9 Q. Yes.

10 A. No, I'm not qualified. I could prepare them,  
11 but I cannot administer. The fact is I am only  
12 allowed IM injections.

13 Q. So I guess my question is, doctors take a  
14 Hippocratic oath not to -- to do no harm, right? Do  
15 you take a similar oath?

16 A. Yes. We take a pharmacist's oath, oath of a  
17 pharmacist, yes.

18 Q. So could a pharmacist administer lethal  
19 injection chemicals that would result in the death of  
20 a person?

21 A. Well, it would depend if the pharmacist is  
22 retired, not practicing anymore. I mean, I'm  
23 assuming there are.

24 Q. Okay. You are saying somebody who is not  
25 practicing?

1 A. Sure.

2 Q. Okay. It would have to be a nonpracticing  
3 medical professional, is that what you are talking  
4 about?

5 A. That would be a good example.

6 Q. Okay. Can a layperson be trained and given  
7 instructions on preparing and administering lethal  
8 injection chemicals under the protocol?

9 A. They can be, but it has to be a lot more  
10 detail than what the people that were involved here  
11 have. You need to have more extensive training,  
12 significantly more extensive training.

13 Q. Tell me what more extensive training you  
14 think needs to be provided.

15 A. For the executioner?

16 Q. Yeah.

17 A. Or the procurer?

18 Q. The executioner.

19 A. So my recommendation would be to have a  
20 pharmacy technician prepare the medication, somebody  
21 who is familiar with how the medication should be  
22 handled aseptically.

23 If you care to have a pharmacy technician  
24 prepare the medications, then a layperson that goes  
25 through a thorough training, perhaps a pharmacy

1 technician course in aseptic technique, not just a  
2 random pharmacy technician course, but maybe an  
3 aseptic technique course, could potentially be  
4 trained.

5 Q. So let's back up. Let me back up a second.

6 We are talking about what training a  
7 layperson needs to administer, prepare and administer  
8 the lethal injection chemical, so I want you to tell  
9 me what training they need to have.

10 A. Right. So my recommendation would be a  
11 pharmacy technician training to compound, to put  
12 medications together to prepare the doses.

13 And then for administration, some type of  
14 a nurse or something that will in detail prepare you  
15 how to prepare the medications, how to administer the  
16 medications.

17 Q. And what would that -- what would that  
18 administration training involve?

19 A. The basics of how to handle the medication,  
20 administer. I'm not a nurse, so I really cannot  
21 recommend a specific -- I can make recommendations on  
22 the pharmacy side.

23 I cannot make specific recommendations  
24 for a level of training on the nursing side, but it  
25 should be somebody who has some type of training that

1 qualifies them to handle and administer medications  
2 appropriately.

3 Q. So tell me what would be involved in the  
4 pharmacy tech training in terms of preparing that you  
5 think they need to be aware of.

6 A. Number one, aseptic technique; how not to  
7 touch critical sites; how to accurately handle  
8 medications. There are certain procedures, and I  
9 teach -- I teach these courses.

10 So, I mean, it's a really long list, but  
11 it includes things like how you reconstitute  
12 medications; how do you know if you have a correct  
13 volume; how do you equilibrate pressure within the  
14 vial and, you know, the solution when you are, you  
15 know, pulling up a certain amount or reconstituting.  
16 You know, these kind of really basic skills that you  
17 need, you know.

18 How do you assure that the medication  
19 will not be contaminated? How do you handle the  
20 syringe and needle, you know? How do you hold it?

21 I mean, they seem like simple things, but  
22 they are not. You know, what our instincts naturally  
23 tell you how we handle things is very different when  
24 we handle sterile preparations.

25 You know, the way you even attach the

1 needle to the hub, there is a technique for that.

2 The way that you inject. What can you hold when you  
3 are pushing the needle into an IV bag. What can you  
4 touch when you are handling the vial?

5 I mean, those are very -- like I said, it  
6 sounds simple to a lay person because it seems like a  
7 no-brainer, but it is not.

8 Q. What in terms of preparation did you -- what  
9 issues did you see with the way that the executioner  
10 described how he handled and prepared the  
11 medications?

12 A. Right. Well, there was a number of things  
13 from his description that were incorrect.

14 Q. Are you -- have you put them in there in the  
15 report?

16 A. Yes. Yes, so --

17 Q. Let's go -- hold on a second, I want to go  
18 through some of them.

19 In paragraph 16 you talk about, as I  
20 understand it -- and correct me if I'm wrong. This  
21 has to do with preparing the vecuronium bromide or  
22 drawing the vecuronium bromide and potassium chloride  
23 into syringes two hours before execution; is that  
24 fair?

25 A. Yes.

1 Q. You understand the midazolam in lethal  
2 injection executions has been drawn into syringes  
3 right before its use? Have you ever seen that?

4 A. Yes. I'm not sure why was there a difference  
5 in the person administering the midazolam versus the  
6 other medications.

7 Q. Let's talk about this. So the reason for  
8 that is, you are saying under USP 797 -- well, let's  
9 talk about this.

10 The vecuronium bromide is not a  
11 compounded preparation?

12 A. Correct.

13 Q. All right. But you are saying drawing it  
14 into the syringe makes it immediate use?

15 A. Correct, because it is not prepared inside of  
16 an ISO Class 5 environment.

17 Q. Right.

18 A. So if you had a sterile hood, you could  
19 extend it beyond use date. But if it's prepared  
20 what's considered bedside, you will need to use it  
21 immediately.

22 Q. And "immediately" is what?

23 A. Within one hour.

24 Q. Within one hour. So we are talking about  
25 vecuronium bromide and potassium chloride, right?

1 A. Right.

2 Q. What is your specific concern about waiting  
3 two hours to administer 100 milligrams of vecuronium  
4 bromide? What's the specific concern?

5 A. We don't know the storage conditions of the  
6 preparation. Is it laying in the room? What's the  
7 temperature of the environment? Has it been exposed  
8 to any temperature?

9 I mean, you start having degradation the  
10 moment you are constituting the vial.

11 Q. So if it was -- if syringes -- if 100  
12 milligrams of vecuronium bromide was in a syringe at  
13 room temperature for an extra hour, what would be  
14 your specific concern that could happen?

15 A. There might be microbial contamination.

16 Q. What kind of microbial contamination?

17 A. Stemming from improper -- I guess not even  
18 improper; just compounding in a non-ISO Class 5  
19 environment.

20 Q. Drawing it into the syringe?

21 A. Right.

22 Q. Okay. What type of contamination are you  
23 talking about?

24 A. So when you are compounding outside of the  
25 ISO Class 5 environment, you basically are talking

1 about compounding in the open with no protection from  
2 any kind of a contamination.

3 So when you -- as opposed to if you  
4 compound in a cleanroom in a hood, you have a HEPA  
5 filter in front of you and you have laminar airflow  
6 that's coming at you of the sterile HEPA-filtered  
7 air, right?

8 So when you are compounding in a hood,  
9 you have this ultra-clean air that's basically  
10 washing all over your sterile sites, over your  
11 critical sites, so there should be no presence of any  
12 bacteria or any chemicals or any kind of particles,  
13 because it is a particle-free HEPA-filtered air.

14 When you are compounding at bedside, you  
15 know, you are in the air. Just because I don't see  
16 dust, it doesn't mean that it is dust free. There is  
17 dust. There are microbial type of contaminants;  
18 maybe a tiny hair.

19 I mean, there's a lot more going on in a  
20 nonclassified or unclassified space when we are  
21 talking about compounding. And so --

22 Q. When you are talking --

23 MS. LEONARD: I'm sorry. Scott, can you  
24 let her finish, please.

25 ///

1 BY MR. SUTHERLAND:

2 Q. Yeah. When you are talking about compounding  
3 in this context, you are talking about drawing it  
4 into the syringe? Is that what you are saying?

5 You are using the word "compounding."  
6 Are you talking about when you draw it into the  
7 syringe?

8 A. Yeah, reconstituting.

9 Q. So I heard what you just said. My question  
10 to you is: What would be your -- okay. You say a  
11 hair or something like that.

12 My question is: What would you expect to  
13 be the specific -- a specific problem that would  
14 occur by leaving it in there an extra hour?

15 A. Potential for contamination.

16 Q. Okay. And what kind of contamination would  
17 you be afraid that might happen?

18 A. Any kind; chemical. Could be a particular.  
19 Could be microbial.

20 Q. Okay. And that vecuronium bromide that  
21 gets -- 100 milligrams that gets injected into the  
22 inmate, what would be your concern about that,  
23 assuming that that individual was going to be  
24 administered a lethal dose of potassium chloride  
25 within a very short period of time after that?

1 A. I don't know, because I don't know what type  
2 of contamination could happen because the environment  
3 is not controlled.

4 Q. So your testimony is you think that there's  
5 contamination that could occur?

6 And it's the same with the potassium  
7 chloride, you are saying that you think that there  
8 could be contamination of the potassium chloride and  
9 the vecuronium bromide that would have an effect on  
10 the inmate, even though they were going to be dead  
11 within five to eight minutes?

12 A. Well, it's the unpredictability that's the  
13 concern. You don't know what could happen, because  
14 you don't know what type of a contamination could  
15 happen.

16 You don't know what type of, you know --  
17 what could be in the vial, so how could you with  
18 certainty say that it's going to work? You don't  
19 know.

20 Q. We are talking about sterility? That's what  
21 we are talking about, right?

22 A. I did mention you could have a physical or  
23 chemical contamination as well when you are working  
24 in an unclassified space.

25 Q. Would you expect the vecuronium bromide and

1 the potassium chloride, would you expect there to be  
2 a potency or sterility problem by being in the  
3 syringe an extra hour?

4 A. There could be.

5 Q. I'm asking you, would you expect there to be?

6 A. That's a very confusing question, because it  
7 would really depend on the conditions of how the drug  
8 was prepared and stored and who prepared it and how  
9 it was laying for an hour.

10 I would be very concerned if the room was  
11 warm; if the person touched critical sites. If  
12 the -- you know, if there's a potential for  
13 contamination as in, you know, in the room, if the  
14 room was maybe dirty.

15 So there are a lot of -- I can't answer  
16 with certainty because I'm not given enough  
17 information to make that statement.

18 Q. Well, let me ask you this. In just an  
19 average room like at a prison with room temperature,  
20 would you expect an extra hour of the vecuronium and  
21 the potassium chloride -- would you expect, in your  
22 professional opinion, there to be a problem with the  
23 potency or sterility of those medications?

24 A. Well, it depends on who prepared it. Was it  
25 a drug preparer who was touching the critical sites

1 as he was preparing it?

2 Q. I think what I'm wanting to know is, would  
3 you expect that those drugs aren't going to do what  
4 they are supposed to do, which is paralyze and stop  
5 the heart?

6 For sitting in there for an extra hour,  
7 would you expect they are not going to perform what  
8 they are supposed to do?

9 A. Again, I think the question really is, when  
10 they were reconstituted, how were they handled. Are  
11 we talking about -- okay, you said they will be in a  
12 proper room temperature, but who handled them and how  
13 were they prepared?

14 If you had a drug procurer handling them  
15 where he's touching the needle in the critical sites  
16 and there's a really strong potential that the  
17 medications will be contaminated, then I would be  
18 concerned.

19 Q. My question to you is, based on what's  
20 paragraph 16 in your report, which the paragraph 16  
21 says that there is a problem because these drugs  
22 weren't administered within an hour.

23 And I'm asking you, if they are  
24 administered within two hours, would you expect they  
25 are not going to have the effects that you would

1 normally expect from vecuronium and potassium  
2 chloride?

3 A. So from the pharmacy practice perspective, I  
4 would not use them. We do not use expired  
5 medications on patients.

6 Q. That's not my question. My question is:  
7 Based on the time alone, would you expect that these  
8 drugs will not do what they are supposed to do?

9 A. I would not know that. It would have to be  
10 tested to see what happened. And that's why I would  
11 not use them.

12 You see, those guidances in USP are there  
13 for a reason. The reason that the USP cites and says  
14 they should not be used after an hour, there  
15 obviously must have been examples when the one hour  
16 was sufficient amount of time to degrade the  
17 medication, and so that's what I go by.

18 The chapter says that you cannot use them  
19 after an hour. It's a simple guidance that you  
20 followed.

21 Q. My question to you is: Do you expect, based  
22 on your experience and your knowledge of these drugs,  
23 would they do what they were supposed to do, sitting  
24 in a syringe for an extra hour?

25 MS. LEONARD: Objection, asked and

1 answered.

2 BY MR. SUTHERLAND:

3 Q. Do you have an opinion?

4 A. I don't, because truth be told, there is not  
5 enough information for me to make that decision.

6 Q. You said that -- your paragraph 16 says  
7 there's a problem with them being expired. I get  
8 that.

9 My question is, okay, generally speaking,  
10 would you say, in the absence of anything else, would  
11 the presence in the syringe just for an extra hour  
12 make them not do what they are supposed to do?

13 A. You know, you say an extra hour as if it  
14 didn't matter. But, you know, one hour extra is  
15 double the time of what the expiration was. The  
16 expiration was set to one hour, and now we are  
17 talking about two hours.

18 So if the USP said not to use it after an  
19 hour, I certainly wouldn't use it after it's sitting  
20 in a syringe for two hours.

21 Keep in mind also, let me just bring this  
22 up as well because this is also concerning, is that  
23 the syringes that these medications are compounded  
24 in -- not compounded, reconstituted and pulled up in,  
25 those syringes are meant for delivery.

1                   They are not meant to store the  
2 medications. So they are not airtight. They are  
3 not, you know, completely enclosed like a container  
4 would be, like a glass vial. You know, a glass vial  
5 is sealed. The syringes are not airtight.

6 Q.           Is the fact that -- isn't the fact -- are you  
7 aware of how many lethal injection executions  
8 Tennessee has done since 2018, Dr. Almgren?

9 A.           No, I'm not aware of how many.

10 Q.          Are you aware that there have been lethal  
11 injection executions since 2018?

12 A.          I have not looked, so I cannot say that I do.

13 Q.          Are you aware that this protocol has been  
14 used since 2018?

15 A.          Yeah. I mean, of course, yes. If you are  
16 asking whether I know that there have been  
17 executions. I guess I missed -- maybe I didn't come  
18 across clear.

19 Q.          Okay.

20 A.          I'm aware that the protocol has been used  
21 and, yes, I'm aware that the lethal injection has  
22 been used. Yes, that's true. I have not looked  
23 specifically at how many. I think that's what  
24 stopped me a little bit.

25 Q.          In paragraph 17 you say: The executioner

1 does not have any special advanced aseptic technique  
2 training.

3 And I guess what I would want to know is,  
4 again, in the context of a lethal injection execution  
5 where death is going to occur within 15 minutes, what  
6 is your specific concern about aseptic training?

7 A. Well, my concern is that you may end up  
8 contaminating the products and they will not act as  
9 they are expected to.

10 If that happens, okay, maybe the final  
11 effect will be what it is. However, it's the time  
12 before that happens, mainly through suffering, pain,  
13 because of potentially the medication is taking  
14 longer than they should to act, maybe causing severe  
15 irritation because they are contaminated.

16 Those are all factors that play into the  
17 fact that you have a person who is preparing a  
18 medication who is not qualified, and so they really  
19 are not taking all of the precautions and all of the  
20 proper steps.

21 Q. Let's use the specific example that you talk  
22 about in paragraph 19, the executioner describes how  
23 he cleans the needle.

24 A. Yes.

25 Q. This is completely an inappropriate and

1 incorrect aseptic technique, in violation of  
2 USP 797. The needle is sterile when taken out and  
3 should not be touched.

4 So if the needle was touched with -- if  
5 it was touched with a saline alcohol swab, what would  
6 you expect the result or the effect of that to be on  
7 the medication?

8 A. No, it's a terrible practice. This is  
9 totally unacceptable. And if I saw any of my  
10 students or pharmacy technicians do that, they would  
11 fail the course or be fired. It's step one of  
12 learning proper aseptic technique. You do not touch  
13 sites.

14 They are critical sites, and you are  
15 really increasing potential for contamination in that  
16 point, because -- for example, so you say he's,  
17 perhaps, using alcohol wipe to wipe the needle. But  
18 is it a sterile alcohol wipe?

19 You know, they sell the alcohol wipes  
20 that are nonsterile. So you want to make sure they  
21 are sterile alcohol wipes, because the nonsterile  
22 alcohol wipes actually sometimes contain spores.

23 The second concern itself is, so you are  
24 wiping the needle with alcohol. So now the needle  
25 has alcohol on it, so when you are injecting and

1 pushing the needle into the vial, now you are  
2 introducing remnants of the alcohol into the  
3 solution, so you are contaminating it further with  
4 the alcohol, potentially.

5 Another concern is now the needle is wet  
6 because it is wet from the alcohol wipe. So now it's  
7 sort of sticky, and so even better chance for, I  
8 don't know, dust particles, maybe, I don't know, any  
9 kind of a little particle that's floating around in  
10 the air sticking to the needle and being introduced  
11 into the solution.

12 Q. What would you --

13 A. Also -- I'm sorry. Also, the alcohol wipe  
14 itself has fibers because it is woven, and so the  
15 fibers themselves may attach themselves to the  
16 needle, and they can also introduce into the  
17 solution.

18 Q. What would you expect the type of  
19 contamination to be that could result? Give me some  
20 examples.

21 A. Alcohol, dust particles, fiber from the  
22 cloth.

23 Q. My question is: What would you expect the  
24 results of that contamination to be on the  
25 medication?

1 A. So alcohol -- I do not know, because I have  
2 not looked into this part. But I wonder if the  
3 alcohol itself, if it is isopropyl alcohol, if that  
4 would potentially react with the chemicals in the  
5 injection and maybe partially degrading some of them.  
6 I don't know. I can't say. Dust.

7 Q. What else?

8 A. Dust particles could be introduced, and they  
9 can cause occlusion of the blood vessel. Fiber, the  
10 same thing.

11 Chemicals, let's say something was  
12 floating in the air and it had some type of -- you  
13 know, maybe they cleaned right before and there are,  
14 you know, particles of cleaner still floating in the  
15 air, that can be introduced. So you could have  
16 chemical contamination from just picking up things in  
17 the air, dust particles, fiber.

18 I mean, there are a lot of different  
19 potential. Again, you are working in an unclassified  
20 space. And I'm not sure how clean the prison is, but  
21 my assumption is it's probably not extremely clean.

22 So my assumption is that there's a very  
23 good potential for dust and dirt and microbial  
24 contamination being in the air just from the nature,  
25 probably fungus. I mean, it's all probably floating

1 in the air.

2 Have there been any studies done on the  
3 air quality? Potentially not.

4 Q. Yeah. Have you been presented any  
5 information about air quality of the prison?

6 A. No. And that would be something that would  
7 be useful.

8 Q. In paragraph 22 you talk about visual  
9 inspection.

10 A. Yes.

11 Q. Is this the type of visual inspection you  
12 always perform?

13 A. Yes. So when you prepare a sterile compound,  
14 you need to perform visual inspection. So there's a  
15 specific procedure that you need to follow.

16 So you look at the product. You look --  
17 you are supposed to look against the light background  
18 and against the black background so you can detect  
19 any particles in contrasting colors.

20 So then you are supposed to flip over the  
21 syringe or vial, whatever you are compounding, or  
22 bag. Not too violently, because you may create air  
23 bubbles forming. So you want to flip it over in kind  
24 of a slower motion and just watch for any kind of a  
25 particle.

1                   So it is a procedure that, again, we  
2       teach in a sterile compounding course to make sure  
3       that those who prepare sterile compounds know how to  
4       prepare them.

5       Q.       Are you talking about the compounding  
6       process?

7       A.       Oh, every constitution when you get ready --  
8       during compounding or during reconstitution when you  
9       are getting ready to -- you know, whenever you have a  
10      finished product.

11      Q.       Is it your opinion that in hospitals,  
12      whenever healthcare professionals are administering  
13      compounded injectables, that they do this -- that  
14      they hold it up against white and black all of the  
15      time?

16      A.       So keep in mind that this is a different  
17      scenario. So it's one thing when in the hospital I  
18      compounded it in our downstairs pharmacy, and then I  
19      send it to the floor. So the nurse is getting the  
20      product within a few minutes, maybe.

21                   You know, so I have done the examination.  
22      It has not been stored. It has not been sitting  
23      around. Or even if it has, it's a relatively short  
24      amount of time.

25                   And the nurses still do look. They don't

1 do the black and white background, but if you had a  
2 procedure during which you have reconstituted or  
3 compounded the product, you definitely need to  
4 perform a visual inspection, because you are not sure  
5 that all of the drug -- like let's say if it's a  
6 reconstitution, has all of it gone to solution? You  
7 need to perform visual inspection.

8 Q. You specifically mentioned in paragraph 22  
9 that you are aware that the executioner does perform  
10 a visual inspection of these chemicals, aren't you,  
11 from his testimony?

12 A. I thought he said that the color of the drug  
13 is not a large focus of mine. I have that stated in  
14 a statement.

15 So it appears that if he does it, he  
16 really doesn't look for the attributes that he's  
17 supposed to. I don't know that he really knows what  
18 goes into doing a visual inspection.

19 Q. And you say: The absence of this procedure  
20 using the black and white background during the  
21 executioner's sterile preparation is very concerning,  
22 as there have been issues with the potassium chloride  
23 prepared for TDOC falling out of solution?

24 A. Correct.

25 Q. What specific issues are you referring to?

1 A. So there were in the reports statements where  
2 they had issues with preparing the potassium  
3 chloride, and the potassium chloride had fallen out  
4 of solution.

5 Q. At the pharmacy?

6 A. Yes. That can happen because it's a very  
7 concentrated solution of potassium chloride. So  
8 those types of -- you know, it's not a good thing,  
9 but it can happen.

10 There are other drugs that fall out of  
11 solution sometimes, and so this is where it's very  
12 important that you examine the solutions prior to  
13 injecting.

14 Q. You are not aware of any situation where the  
15 potassium chloride has fallen out of solution at the  
16 Department of Corrections after it's been received,  
17 are you?

18 A. Well, the executioner is not performing a  
19 visual inspection. So, obviously, I only can use the  
20 records that I have. So if he is not performing a  
21 visual inspection, how would I know?

22 Q. Are you aware of any compounded potassium  
23 chloride that's gone to the Department of Corrections  
24 that has fallen out of solution?

25 A. Again, how would I know when it's not being

1 examined? I'm not at the Department of Corrections,  
2 so I do not see the products.

3 So if the drug procurer and the  
4 executioners do not perform the visual inspection,  
5 then they don't -- then there is no record of it. It  
6 doesn't mean it didn't happen, it's just that they  
7 have not looked.

8 Q. Now, the records show that there were samples  
9 that were prepared, or batches that were prepared  
10 that may have fallen out of solution, but you don't  
11 have any information that any potassium chloride that  
12 have fallen out of solution was ever sent to the  
13 department, do you?

14 You are not saying that the pharmacist  
15 sent the TDOC potassium chloride that had fallen out  
16 of solution, are you?

17 A. I would have to go back and look and see what  
18 exactly this statement from the procurer said,  
19 because I do see in my statement that there have been  
20 issues with potassium chloride prepared falling out  
21 of solution.

22 And I do remember a procurer stating that  
23 that was the case. And, of course, the pharmacist  
24 did as well. So I would need to go back to that  
25 statement and see what exactly was said.

1 Q. Do you think that the Department of  
2 Corrections has been sent potassium chloride that has  
3 fallen out of solution at the pharmacy?

4 A. How would I know? I don't know.

5 Q. I'm asking you, based on what you reviewed,  
6 do you think that they have sent --

7 A. Well --

8 Q. -- potassium chloride that's fallen out of  
9 solution?

10 A. So let me just point out another thing that  
11 can happen. What can happen sometimes --

12 Q. Answer my question first. Do you think that  
13 the pharmacist has sent potassium chloride to the  
14 department that has fallen out of solution based on  
15 what you reviewed?

16 A. So they can send the solution that maybe does  
17 not have a precipitant. But by the time it gets to  
18 the Department of Corrections --

19 Q. You are not answering --

20 A. -- the solution.

21 Q. Stop. Stop. You are not answering my  
22 question.

23 A. Why can't I finish my statement?

24 Q. Well, because you are not answering my  
25 question.

1 I'm asking you first: Do you have any  
2 information that the pharmacist in this case sent the  
3 Department of Corrections any potassium chloride that  
4 had fallen out of solution?

5 A. So this is a tricky question, because I do  
6 not know which batches were sent to the Department of  
7 Corrections --

8 Q. I'm asking you if you know if they have.

9 MS. LEONARD: Please let her finish her  
10 answer.

11 MR. SUTHERLAND: She is not answering my  
12 question. I'm asking her to answer my question.

13 MS. LEONARD: I think she is trying to  
14 answer the question. If you could let her finish,  
15 then we could see.

16 This has happened now two or three in a  
17 row. Could you please let her try to finish?

18 THE WITNESS: So what I was saying is I  
19 do not know which batches were exactly sent to the  
20 Department of Corrections, because I see the quality  
21 records from the pharmacy, I saw the pharmacist's  
22 statement that they had issues, but as to which  
23 specific batches were sent and received, those  
24 records are marked out, and I really cannot see which  
25 lot number corresponds to which product and if there

1 were any quality issues.

2           So long story short, I do not know the  
3 answer to your question. And to elaborate further,  
4 sometimes you can send a product that maybe in a  
5 pharmacy appears fine, but during the transport, if  
6 it's maybe exposed to inappropriate temperatures,  
7 maybe too high or too low, it may precipitate by the  
8 time it comes to the customer.

9 BY MR. SUTHERLAND:

10 Q.       So I'm going to ask you to answer my  
11 question, which is: Do you have any information that  
12 the pharmacist that compounds potassium chloride for  
13 the Tennessee Department of Corrections has sent  
14 potassium chloride that has fallen out of solution to  
15 the department?

16 A.       No, because I don't have enough -- any  
17 records to review specific to that.

18 Q.       When a medication falls out of solution, what  
19 do you do with it?

20 A.       So it depends on the type of medication.  
21 Some medications, when they fall out of solution, you  
22 can't really reconstitute.

23           As in the precipitant stage, it degrades  
24 the medication, and that's -- typically most of the  
25 time we do not use it.

1                   There are some medications where  
2       precipitation is common, and so the dose we might be  
3       able to reconstitute or whatever and it can be  
4       corrected. But a lot of medications, once you have  
5       the precipitant, you would not use it.

6       Q.           You don't know what they did with it here?

7       A.           No.

8       Q.           Okay. If we could look at Section 5 of  
9       Number 4, it says: Instructions for lethal injection  
10      chemicals preparation are not detailed and specific  
11      enough, and may result in the administration of the  
12      wrong dose.

13                   In paragraphs 23 and 24, are you talking  
14      about the instructions for preparation of midazolam  
15      and potassium chloride?

16      A.           Right. So from the depositions it appeared  
17      that obviously in the protocol you have some standard  
18      directions on how to prepare, but there were also --  
19      what was mentioned in the depositions was that the  
20      pharmacy would actually send a document on how to  
21      properly reconstitute or prepare the medication, so  
22      they had a separate document that was dealing with  
23      specific medications.

24      Q.           So I'm going to ask you the question again.  
25      Are you talking about the midazolam and potassium

1 chloride instructions --

2 A. Let me look.

3 Q. -- in paragraphs 23 and 24?

4 A. I believe it's both.

5 Q. Okay. Did you review those instructions?

6 A. Yes.

7 Q. The written instructions?

8 A. Yes.

9 Q. Well, can you tell me what the specific  
10 concerns you had about each specific instruction?

11 A. So I don't have concerns as in the  
12 instructions alone. My concern is that when you have  
13 instructions coming with the medications, what if  
14 the -- what if a mix-up happens and you don't have  
15 the correct instructions and using instructions from  
16 the older drugs, because it appears that they had  
17 vials from different batches.

18 And so you would want to make sure that  
19 you are using the proper instructions in the product  
20 that it came with.

21 Q. Do you have any problems with the  
22 instructions you reviewed?

23 A. No, they were specific to the product.

24 Q. Okay. So of the instructions you reviewed of  
25 midazolam and potassium chloride, you had no problem

1 with the instructions?

2 A. Well, I do have a problem in the sense that  
3 they are written more for a professional. They  
4 really should be broken down in much smaller and more  
5 pointed steps, because I feel like the executioner  
6 who prepares the medications may not be really  
7 familiar with all that goes into drug preparation,  
8 could probably benefit from having more detailed  
9 instructions.

10 Q. What detail would you want to be in there  
11 that's not in there?

12 A. Can you open the instructions, and I'll tell  
13 you?

14 Q. I don't have them. I'm wondering -- I'm  
15 looking at your report and I'm trying to figure out  
16 what specific problems you have with the  
17 instructions.

18 A. I mean, I think they are summarized from --  
19 yeah, I think they were just summarized by the  
20 executioner.

21 Q. There were written instructions provided --

22 A. In the protocol, yes.

23 Q. No. There are separate written instructions.

24 A. Yes. Right.

25 Q. Have you seen those?

1 A. I'm trying to remember. I thought I did. I  
2 thought I saw something, but I'm not a hundred  
3 percent sure.

4 MS. LEONARD: I think maybe it would be  
5 helpful if we pulled up the document that you are  
6 talking about so we can make sure we are all talking  
7 about the same thing here, please.

8 MR. SUTHERLAND: I don't have -- I don't  
9 have it. Do you have it, Lynne?

10 MS. LEONARD: I do, yeah. Would you like  
11 me to send that over to you?

12 MR. SUTHERLAND: Sure. Actually, just  
13 send it to Rob. Send both of them, if you can.

14 MS. LEONARD: It might take me a second  
15 to find them here, but I'm looking. I know I do have  
16 them.

17 MR. SUTHERLAND: I think they were in  
18 like the first 15 exhibits of you-all's deposition  
19 exhibits.

20 MS. LEONARD: Yeah. Midazolam and the  
21 potassium chloride, that's what you need?

22 MR. SUTHERLAND: Yeah.

23 MS. LEONARD: I should send them just to  
24 Rob right now?

25 MR. SUTHERLAND: Yeah. You can send it

1 to both of us.

2 MS. LEONARD: I'll copy Alex. Do you  
3 want me also to send them to Dr. Almgren and send  
4 them back --

5 MR. SUTHERLAND: No, you can send them to  
6 her so she can see them.

7 MS. LEONARD: Great. I just wanted to  
8 make sure that we are talking about the same  
9 documents here.

10 MR. MITCHELL: I received them. Thank  
11 you, Lynne.

12 MS. LEONARD: Sure thing. And I also  
13 just sent them to you, Dr. Almgren. It may take a  
14 minute with the delay, but hopefully everyone can  
15 pull them up soon.

16 MR. MITCHELL: Do you want me to pull up  
17 potassium chloride, midazolam?

18 MR. SUTHERLAND: Midazolam to start.  
19 That will be Exhibit 6.

20 Let me know when you have them,  
21 Dr. Almgren.

22 THE WITNESS: I see them on your screen,  
23 I have not seen them yet.

24 Do you mind if I take a five-minute  
25 break?

1 MR. SUTHERLAND: That would be perfectly  
2 fine. Let's say 2:15.

3 (An off-the-record discussion was held.)

4 (WHEREUPON, a document was marked as  
5 Exhibit Number 6.)

6 MR. SUTHERLAND: Rob, if you could put up  
7 what's going to be Exhibit 6, which is the midazolam  
8 instructions. Rob, can you put up the midazolam  
9 instructions, which will be Exhibit 6? Thank you.

10 BY MR. SUTHERLAND:

11 Q. Dr. Almgren, were you able to look through  
12 these?

13 A. I'm looking at them right now. Yes, I got  
14 them right as I sat down.

15 Q. Have you seen these before?

16 A. I have. I do believe I've seen them.

17 Q. Okay. And are these the instructions that  
18 you are talking about in paragraph 23?

19 A. Yes.

20 Q. And the concern that you identified in  
21 paragraph 23, as I understand it, is because you  
22 understand the instructions that come with a new  
23 batch of drugs might differ, that they might be  
24 confused with the previous instructions?

25 A. Sure.

1 Q. In paragraph 23 you don't identify any  
2 specific problems with these instructions, do you?

3 A. I mean, I did not address anything in terms  
4 of specifics.

5 Q. Okay. And in paragraph 24, you say --

6 MR. SUTHERLAND: Rob, you can put up the  
7 potassium chloride instructions, that will be  
8 Exhibit 7.

9 (WHEREUPON, a document was marked as  
10 Exhibit Number 7.)

11 MR. SUTHERLAND: Just to confirm,  
12 Dr. Almgren, have you --

13 THE WITNESS: Now, I do have concerns --  
14 are you asking me -- I'm sorry.

15 Are you asking me --

16 BY MR. SUTHERLAND:

17 Q. I'm asking you what's -- ma'am, what I'm  
18 asking you is, in your report you identify issues  
19 with the instructions in paragraph 23, right?

20 A. Yes.

21 Q. Okay.

22 A. What I'm reading right now.

23 Q. Section 5 of your report deals with the  
24 instructions?

25 A. Yes.

1 Q. Okay. And in paragraphs 23, 24 and 25 you  
2 address the instructions.

3 And I asked you if the instructions that  
4 you are talking about in 23 are the midazolam and  
5 potassium chloride instructions. And I  
6 understand the answer is yes; is that correct?

7 A. That's correct.

8 Q. Okay. And the concern that you raise about  
9 these instructions, midazolam and potassium chloride  
10 in your report, is that they might change and that  
11 the executioner might not be able to determine which  
12 ones should be used.

13 Is that what you say in paragraph 23?

14 A. Yes.

15 Q. I'm sorry?

16 A. Yes.

17 Q. Okay. In paragraph 24 you say, "The protocol  
18 also provides some general instructions for the  
19 preparation of two sets of syringes."

20 A. Now, that is referring to the protocol, the  
21 lethal injection protocol.

22 Q. Correct, yes. "Depending on the LIC supply,  
23 the procedure may be completely different."

24 And you are talking about the distinction  
25 between compounded and commercially available, right?

1 A. Yes.

2 Q. And you are talking about getting that  
3 confused, is that what you are referring to?

4 A. Yes. There could be potential for medication  
5 error. How would your executioner know, let's say,  
6 if vecuronium came all a sudden compounded, but the  
7 instructions in the protocol say to, you know,  
8 reconstitute.

9 You know, it's not -- the instructions --  
10 it's a little confusing, I think, for a layperson to  
11 keep up with what needs to be prepared according to  
12 what instructions, especially if something were to  
13 change.

14 MR. SUTHERLAND: We'll make the midazolam  
15 and potassium chloride instructions Exhibits 6 and 7.

16 BY MR. SUTHERLAND:

17 Q. In Section 8 -- I'm sorry.

18 In Section 6 of your report you talk  
19 about: The procedures described in the protocol are  
20 not being followed as written, which can lead to many  
21 potential errors, and I'd like to ask you about that.

22 The first one you mentioned in  
23 paragraph 26 is the protocol requires LIC on hand to  
24 be monitored for expiration dates?

25 A. Yes.

1 Q. And that that procedure is not being  
2 followed?

3 A. Right.

4 Q. Do you have information to believe currently  
5 that TDOC has ever used any expired LIC?

6 A. So in one of the testimonies I had a  
7 question, because I did read one of the statements  
8 and it did appear that the medication -- and, again,  
9 I can only use the records that I have. I was not  
10 there.

11 Q. Yeah.

12 A. And so I can only look and see what you had  
13 at the time and what was legible as well, and what's  
14 also not redacted. So those are some of the issues  
15 that I ran into.

16 It's sometimes difficult to trace which  
17 medication are we talking about. But to the best of  
18 my abilities, I was trying to follow to see if there  
19 were any medications that could potentially have been  
20 used that were expired, so --

21 Q. Do you have any -- and maybe we are getting  
22 to that, but in paragraph 27 you talk about midazolam  
23 for Donnie Johnson.

24 A. Yes.

25 Q. And I want to talk about that one in a

1 minute.

2 Other than that, do you have any other  
3 information that the TDOC has ever used an expired  
4 LIC?

5 A. Do I have any information?

6 Q. Yes. Do you have any information in front of  
7 you, other than what we are going to talk about in  
8 paragraph 27, that the TDOC has ever used any expired  
9 lethal injection chemical?

10 A. Well, the ones that were used two hours after  
11 preparation instead of one hour, those would be  
12 considered expired, so --

13 Q. Let's set that aside. Anything else?

14 A. I can go back and look at the records.

15 Q. As you sit here right now, do you have any  
16 other information?

17 A. No, I don't think so.

18 Q. Okay. So let's look at paragraph 27.  
19 Because you don't mention anything in your report  
20 other than this in paragraph 27, and what we talked  
21 about earlier about the immediate use.

22 So have you -- you say that: The drug  
23 procurer testified based on a log prepared by the  
24 pharmacy there was no unexpired midazolam in TDOC's  
25 possession between May 1, 2019 and July 16, 2019.

1 However, Donnie Johnson was executed on May 16th of  
2 2019.

3 Have you seen records that show you that  
4 Tennessee Department of Corrections did, in fact,  
5 have unexpired midazolam in its possession when  
6 Donnie Johnson was executed since you wrote this  
7 report?

8 A. I don't remember. I believe I had logs of  
9 all of or a majority -- I'm not sure if I had all of  
10 the logs, because I don't know what all records you  
11 had. But I had some logs of the medications and when  
12 they were received and when they were -- what their  
13 beyond use date was or what their expiration was. I  
14 would have to go back and look at the logs that were  
15 provided.

16 MR. SUTHERLAND: Rob, can you pull up, I  
17 guess, what is actually identified as -- it should be  
18 Exhibit 8, but it's going to be Exhibit 6 on what I  
19 gave you. It's records of midazolam for Donnie  
20 Johnson.

21 THE WITNESS: Actually, that statement,  
22 now that I'm reading it, this is something that the  
23 drug procurer had stated. That was in the drug  
24 procurer's testimony or deposition, I should say,  
25 where that statement came from.

1 BY MR. SUTHERLAND:

2 Q. I understand. I just want to make sure that  
3 you have reviewed -- all right.

4 Do you see on page 29 where it says,  
5 "Donnie Edward Johnson, midazolam 50 milligrams  
6 injection solution"?

7 MS. LEONARD: I'm sorry. Are you  
8 planning to send this our way, Rob?

9 MR. SUTHERLAND: Yeah, you have  
10 already --

11 MR. MITCHELL: I'm sorry, I forgot to  
12 send it. Let me unshare and send it. Give me  
13 20 seconds.

14 MS. LEONARD: Thanks. It's fine if you  
15 want to keep going, I just want to make sure that  
16 that's on its way.

17 MR. SUTHERLAND: No, I'll wait until she  
18 has it in front of her.

19 (WHEREUPON, a document was marked as  
20 Exhibit Number 8.)

21 BY MR. SUTHERLAND:

22 Q. Dr. Almgren, it's page 29 of that. This is  
23 the group of documents you were provided that  
24 resulted, as I understand it, in your supplemental  
25 report.

1 A. Got it.

2 Q. On page 9 there's a -- 29, I'm sorry.

3 A. Is this being sent to me as well?

4 MS. LEONARD: Not yet. I don't have it  
5 yet either, unfortunately, but as soon as I have it,  
6 I'll forward it.

7 I just got it. I sent it, so hopefully  
8 another couple of seconds.

9 MR. SUTHERLAND: Let me know when you  
10 have got it, Dr. Almgren.

11 THE WITNESS: So far, nothing. Okay, it  
12 just came through.

13 BY MR. SUTHERLAND:

14 Q. When you open that up, if you would scroll  
15 through those documents and tell me if those are the  
16 38 pages that were provided to you that resulted in  
17 your supplemental report? That's my first question.

18 A. I believe, but I'm not 100 percent sure,  
19 because a couple of these look -- there's a couple of  
20 them upside-down, but I'm not sure they looked like  
21 this in my file.

22 Q. Well, your report says you were provided with  
23 Defendant's Supplemental Response 1118, pages 000001  
24 through 38. Do you think these are the documents  
25 that you got?

1 A. They do look familiar. I'm assuming they are  
2 the same.

3 Q. So I want to take you to page 29.

4 A. Okay.

5 Q. Do you see where it says Donnie Edward  
6 Johnson?

7 A. Yes.

8 Q. And this prescription is dated 4-16-2019, do  
9 you see that?

10 A. Yes.

11 Q. Okay. If that midazolam was frozen  
12 midazolam, how many days is that frozen midazolam  
13 good if it stays frozen?

14 A. Forty-five days.

15 Q. What's roughly 45 days from April 16th?

16 A. So, yes, so 45 days is the general beyond use  
17 date; that's how we establish it by USP.

18 Q. I'm asking you, how many days is 45 days from  
19 April 16th, roughly?

20 A. I guess the end of May, early June.

21 Q. So if this midazolam for Donnie Edward  
22 Johnson was frozen and it was maintained properly at  
23 a frozen temperature, it would have been good until  
24 the end of May, early June; right?

25 A. Well, let me bring this up again.

1 Q. Can you answer that as yes or no?

2 A. No, I cannot, because I have to explain my  
3 answer. I'm sorry.

4 Q. Okay.

5 A. My answer is following. So typically we  
6 establish beyond use date based on USP 797, 45 days.  
7 Yes.

8 However, let's say when I compound and I  
9 have multiple ingredients that I add -- so it's one  
10 thing if I only have midazolam. If the only thing  
11 I'm adding is midazolam into sterile syringe for  
12 injection, and both of them have expiration set by  
13 the manufacturer as a year from now, six months from  
14 now, then I can safely assume that the beyond use  
15 date according to USP 797 would be 45 days.

16 However, if I'm adding multiple  
17 additives, so maybe I adjust the Ph, maybe I'm adding  
18 a stabilizer, so I'm doing a formulation that goes  
19 beyond just these two ingredients, if I add other  
20 ingredients, now I have to look at the expiration of  
21 each ingredient separately.

22 And if any of the ingredients expire  
23 before the 45 days, then my BUD will be that date.  
24 So I cannot -- so following up on that -- I'm sorry.

25 Following up on that, if, let's say, I

1 get a compound from a pharmacy, I cannot -- and it  
2 does not have a BUD written on it, I cannot safely  
3 assume that it is good for the next 45 days, as long  
4 as it's frozen, from the date it was compounded.

5 I have to contact the pharmacy and say:  
6 What is your beyond use date? What did you do?

7 Because a lot of times these excipients  
8 may have a shorter expiration, and so you may not  
9 have 45 days expiration on the product just because  
10 that's normally what's given.

11 Q. Dr. Almgren, what does the prescription say  
12 discard after?

13 A. Where does it say that?

14 Q. Under midazolam.

15 A. 5-31-2019?

16 Q. Yes.

17 A. So that's the prescription. What are you  
18 asking me?

19 Q. It says, discard after 5-31-2019; does it  
20 not?

21 A. All right. But that's written -- that  
22 prescription is not written by the pharmacist; is it?

23 Q. I'm asking you if this record is a -- is part  
24 of a prescription of midazolam that was issued on  
25 4-16-2019 that says discard after 5-31-2019 for

1 Donnie Johnson?

2 A. Who said to discard after? That is my  
3 question. Because that should not be -- I assume the  
4 prescription came from the physician, right?

5 Q. I'm talking about, what does this look like?  
6 Doesn't this look like what comes with prescribed  
7 medication from the pharmacy?

8 A. I do not know. Okay. So my question is,  
9 what is it? I do not know. I am assuming that this  
10 is a prescription.

11 I do not know what it is, because  
12 everything on here, except the name of the person,  
13 the address, and the actual prescription, is  
14 redacted.

15 So for me this was an assumption that  
16 this is a prescription, some type of a medical order  
17 that came across. Is that not what this is?

18 Q. When you pick up a prescription at the  
19 pharmacy, you get a piece of paper that has your name  
20 and the type of medication, and it has the date that  
21 it's -- the 4-16-2019 date, the date that it's given  
22 to the patient --

23 A. Written.

24 Q. -- or written, and then it has a discard date  
25 on it, doesn't that look like what this piece of

1 paper is that comes with the prescription?

2 A. The doctor does not set beyond use date of  
3 the prescription.

4 Q. No, I'm saying --

5 A. It's the pharmacist who does that. So the  
6 discard after 5-31, that may be written by the  
7 physician.

8 Q. Yeah. If the beyond use date on this  
9 prescription for midazolam was 5-31, then the TDOC  
10 had unexpired midazolam; didn't it?

11 A. No. Because, is this a prescription? This  
12 is my -- or is this a label from the vial? I do not  
13 know. What is this record? Please clarify. What is  
14 it?

15 Q. I'm asking you if this prescription was  
16 filled on April 16th, frozen, and it had a 45-day  
17 beyond use date, which would be around the end of May  
18 or first of June, there was no -- there was no  
19 expired midazolam in the possession of TDOC; was  
20 there?

21 MS. LEONARD: Objection to form.

22 THE WITNESS: Can you repeat the  
23 question? I'm sorry, I lost you halfway through.

24 BY MR. SUTHERLAND:

25 Q. I'm going to move on.

1 A. My question for you is -- I can't answer  
2 when -- if this is a prescription, the prescription  
3 is not dated.

4 The doctor is not the one that specifies  
5 beyond use dating. This what you are showing me, is  
6 this a prescription, or is this a label from the vial  
7 or some kind of a transfer record? That is what I  
8 am --

9 Q. This record came from the pharmacy.

10 A. It's confusing.

11 Q. Does that help you?

12 A. Yes.

13 Q. And what does that tell you then?

14 A. Well, that tells you what the -- when it was  
15 prepared and who -- and who it was for, and when it  
16 was to be discarded by, but that is not what the  
17 records said. That's not what the procurer had in  
18 the records.

19 Q. In Section 7, starting on page 10 of your  
20 report, you talk about questionable lethal injection  
21 chemical shipping and storage conditions. I'll talk  
22 to you a little bit about that.

23 In paragraphs 28 and 29 and 32, you talk  
24 about the LICs storage not being properly monitored.  
25 According to what?

1 A. According to the records that were provided  
2 for my review and the procurer's statements.

3 Q. Yeah. You talk about how USP 797 requires --  
4 it is important to monitor temperature regularly to  
5 assure that LICs are stored in acceptable temperature  
6 ranges.

7 How do you monitor temperature ranges  
8 when you give compounded medications to a patient?

9 A. I'm talking about storage conditions.

10 Q. I'm saying, how does the compounding  
11 pharmacist monitor temperatures once they are given  
12 to a patient?

13 A. Well, once they are given to the patient,  
14 they are gone. They have been given to the patient.

15 Q. You don't have any way -- you don't have any  
16 way of monitoring temperatures, do you?

17 A. I don't understand the question. Do you  
18 mean --

19 Q. Well, you --

20 A. No, no. I mean, are you talking about -- the  
21 compounded --

22 Q. Listen to me. Let me ask the question. You  
23 answer the question.

24 Compounding pharmacists compound  
25 preparations.

1 A. Yes.

2 Q. They give them to patients, the patients take  
3 them home. Those compounded preparations aren't  
4 monitored for temperature after they leave the  
5 pharmacy.

6 You are talking about -- the types of  
7 continuous monitoring process you are talking about  
8 is in a hospital setting or at the pharmacy.

9 A. So this is -- keep in mind that these  
10 medications -- we would not dispense a medication  
11 that is to be stored in a deep freeze to a patient to  
12 take home, because nobody at home will have this type  
13 of a freezer setup.

14 So these types of medications would  
15 definitely be stored in a healthcare setting, whether  
16 an oncology practice, home infusion in a hospital; we  
17 have freezers in which we store the medications.

18 I mean, you would not dispense -- I  
19 cannot imagine dispensing like a deep frozen compound  
20 to a patient to take home, unless they are going to  
21 use it within -- you know, they are taking it home to  
22 use right away. But you would not -- this is  
23 something -- you know, this is not a normal, common  
24 practice.

25 And, you know, even according to USP 797,

1 a compounding facility is responsible to ensure that  
2 the compounded sterile products, you know, maintain  
3 their quality until they are administered.

4 So, you know, we will, you know, advise  
5 the patients, you know. Like, for example, if we  
6 dispense a TPN, total parenteral nutrition product,  
7 those need to be refrigerated.

8 So instructions to the patient would be:  
9 Take this home, use it within this long, and keep it  
10 in the refrigerator and, you know, maintain the  
11 temperature.

12 Q. How long?

13 A. A day, two. I mean, it depends on -- you  
14 know, maybe 24 hours. You know, it depends on --

15 Q. Could it be longer?

16 A. I mean, we ask the patient to monitor to make  
17 sure that the temperatures do not get outside of the  
18 range, because that's very, very concerning if you  
19 have a total parenteral nutrition product that's not  
20 stored properly; it's very, very dangerous.

21 Q. Do you think that patients monitor the  
22 temperature of their refrigerators?

23 A. I mean, they need to. And we have -- a lot  
24 of times what we do -- let me finish.

25 A lot of times what we'll do is we'll

1 include a monitoring little strip. It's a part of  
2 the packaging of the product, and basically that  
3 strip will alert you when the product is not to be  
4 used because the temperature has gone outside of the  
5 range.

6 Q. Those are commonly used in a compounding  
7 practice when you are shipping --

8 A. Right.

9 Q. -- compounds, right?

10 A. Yes, exactly. Those are used when you are --  
11 yes, when you are transporting it and you want to  
12 make sure that it stays within the range.

13 Q. In Section 7 of your report you talk about:  
14 Analytical reports for compounded medications are not  
15 in compliance with USP requirements.

16 A. Are we moving on to the second supplemental  
17 report?

18 Q. No. If you look at page 11.

19 A. Page 11, got it. Okay.

20 Q. The majority of analytical reports for  
21 compounded medications are not in compliance with USP  
22 requirements.

23 A. Yes.

24 Q. As per current USP compendium, there does not  
25 appear to be adequate action taken by the pharmacist,

1 drug procurer, or any other TDOC member to address  
2 this issue.

3 You discuss the testing on midazolam and  
4 potassium chloride.

5 When you talk about assay, are you  
6 talking about potency?

7 A. So it can be, yes. Potency and assay can  
8 sometimes be -- you are basically looking to see the  
9 strength or -- you know, sometimes assay can refer,  
10 you are looking at the purity, sometimes it's just  
11 the strength of the solution.

12 Q. So I guess my question to you is, you list  
13 all of the testing for midazolam and potassium  
14 chloride on pages 13 and 14. So what is -- what is  
15 it that you -- tell me your concerns about the  
16 testing that was performed.

17 MS. LEONARD: Objection to form.

18 THE WITNESS: So the testing itself, you  
19 know, there are USP requirements in terms of what you  
20 should test for. And actually your lethal injection  
21 protocol states that the product should be tested as  
22 per USP.

23 So, you know, so you obviously request  
24 this testing to be done, which makes perfect sense,  
25 because for such an important purpose you want to

1 make sure that the medications are potent, that they  
2 have the potency and they are made appropriately.

3 So, unfortunately, the testing shows that  
4 these medications are not always within the specs  
5 that they should be. And then some of the testing  
6 was simply not done.

7 You know, at times -- this is important  
8 testing that really should be done. Like the Ph, why  
9 was Ph not done? I mean, that's an important test  
10 that, you know, basically tells you if the medication  
11 can be applied safely.

12 BY MR. SUTHERLAND:

13 Q. So let me ask you this. As I understand it,  
14 you are saying in paragraph 34 that laboratory  
15 testing for midazolam following the USP monograph for  
16 midazolam injection, it lists these A through F,  
17 right?

18 A. Yes.

19 Q. And so on page 13 you go through the  
20 midazolam, these tests for midazolam, and you say:  
21 None of the compounded preparations of midazolam meet  
22 all USP quality standards because not all of the  
23 tests required have been performed.

24 A. Right.

25 Q. Is that what you are saying the problem is,

1 is that the tests in A through F in paragraph 34  
2 haven't been performed for each?

3 A. Some of them have not been performed. And  
4 there are a couple of instances where the tests  
5 actually were failures. I think there was one where  
6 the assay failed.

7 Q. Which one was that?

8 A. When you look at the next page.

9 Q. The second one?

10 A. Yes.

11 Q. Okay. And do you know what happened to that  
12 midazolam?

13 A. I don't remember. I do not know. Was it  
14 used?

15 Q. I'm just asking you if you know.

16 Do you know what happened to that  
17 midazolam in that entry?

18 A. No.

19 Q. You are not assuming it was used, are you?

20 A. Am I assuming it was used?

21 Q. I said, you aren't assuming that it was used,  
22 are you?

23 A. I hope it was not, considering it didn't pass  
24 the quality control.

25 Q. You don't know what was done with it?

1 A. I'd have to go back and look at the records.

2 Q. So other than that one, your concerns deal  
3 with the lack of completing the A through F tests for  
4 midazolam, right?

5 A. Correct.

6 Q. Okay. And that would be the same on page 14  
7 for the testing of potassium chloride A through E.

8 The one concern you would have would be  
9 that all of the tests in A through E weren't  
10 performed, right, or based on the records that you  
11 saw; right?

12 A. Right. I'm looking and I see that. Yes,  
13 there are a number of failures. The potassium  
14 chloride appears to have a number of failures. There  
15 were two failed products --

16 Q. Right.

17 A. -- with the potency outside of the range.

18 Q. Right. But I'm asking you, one concern you  
19 have is that there are five tests, 37 A through E,  
20 that you would say you don't have a record were  
21 performed? That's one concern, right?

22 A. Well, in my statement I say all of the  
23 samples tested for potency failed, so --

24 Q. If you will just answer my -- if you will  
25 just listen to my question.

1 MS. LEONARD: Scott, can you please let  
2 her finish?

3 MR. SUTHERLAND: Well, I'm trying to  
4 finish my question, Lynne.

5 MS. LEONARD: I know. I think that you  
6 asked a question and she started answering, and then  
7 she was cut off about halfway.

8 MR. SUTHERLAND: Okay.

9 BY MR. SUTHERLAND:

10 Q. My first question to you, Dr. Almgren, is  
11 this: One of the concerns that you have, is it not,  
12 is that in paragraph 37, A through E tests that you  
13 talk about as required and specified by USP for  
14 potassium chloride, one concern you have is not all  
15 of those tests were performed, based on the records  
16 you reviewed; is that correct?

17 A. Correct.

18 Q. All right. And another concern you have, of  
19 course, is that in paragraph 38 there are two tests  
20 for potency that failed; is that correct?

21 A. Yes.

22 Q. You don't know what was done with the  
23 potassium chloride that failed, do you?

24 A. I do not know. What concerns me is the fact  
25 that this pharmacy is having issues with preparing

1 the drugs when the potency fails. That's a very  
2 serious concern that shouldn't have happened.

3 Q. If they prepare potassium chloride that's  
4 sent off for testing and it does satisfy the potency  
5 requirement, that wouldn't concern you; would it?

6 MS. LEONARD: Objection to form.

7 THE WITNESS: Is it the same pharmacy  
8 that prepared all of the previous lots that had  
9 failed?

10 BY MR. SUTHERLAND:

11 Q. Yes.

12 A. I would like to see some more steady record  
13 that they are able to prepare drugs properly, this is  
14 not just the lucky one.

15 Q. So you are saying that if the pharmacy had a  
16 test that said that it passed for potency of  
17 potassium chloride, you would have a problem with  
18 that?

19 MS. LEONARD: Objection to form.

20 THE WITNESS: I wouldn't have a problem,  
21 but I would be concerned. Just as I would be  
22 concerned if I know a pharmacy has problems with  
23 their records, with their quality compounding.

24 I mean, I can ask you the same question.  
25 Would you be comfortable with having medication

1 compounded for your two-year-old in a pharmacy that  
2 has issues with quality? Would you be okay with  
3 that, when you know the pharmacy is having lots of  
4 issues with their compounds that are made  
5 inaccurately?

6 I would not be comfortable with that.

7 BY MR. SUTHERLAND:

8 Q. In Section 10, starting at the bottom of  
9 page 15, you talk about: Compounding logs and  
10 facility records are necessary to ascertain whether  
11 the pharmacy is meeting quality requirements. Do you  
12 see that on page 16?

13 A. Yes.

14 Q. Did you receive some records, compounding  
15 records?

16 A. Yes. I have received some limited number of  
17 pages, some of the compounding records, and I have  
18 supplied an additional supplemental report addressing  
19 those.

20 Q. Let's talk about that. So as I read your  
21 supplemental report, you raised three primary issues.  
22 You can correct me if I'm wrong.

23 One has to do with your review of the  
24 records, indicating that API was obtained from  
25 sources where the API was manufactured under the

1 European Pharmacopeia or the British Pharmacopeia,  
2 and that those APIs haven't been tested against a USP  
3 monograph; is that fair?

4 A. Yes.

5 MS. LEONARD: Objection to form.

6 BY MR. SUTHERLAND:

7 Q. What was your answer, Dr. Almgren?

8 A. Yes.

9 Q. Okay. And tell me a little bit more about  
10 that.

11 MS. LEONARD: Objection to form.

12 THE WITNESS: What exactly would you like  
13 to know?

14 BY MR. SUTHERLAND:

15 Q. Well, the general -- your general objection  
16 to that.

17 A. Well --

18 Q. It says the API that were manufactured under  
19 EP and BP. Once obtained, tell me what the problem  
20 with that is.

21 A. Well, in general, in order to compound and  
22 prepare a USP-grade medications, you have to start  
23 off with a USP grade API, so pharmaceutical grade  
24 according to USP regulations.

25 So when you receive a drug, typically

1 from foreign sources, because that would be the main  
2 reason why they would not have necessarily the USP  
3 quality records -- when you receive these medications  
4 from foreign sources, you definitely need to test  
5 them according to USP, because the USP may have, and  
6 a lot of times it does have, a different set of  
7 standards than the EP or BP.

8 And those different quality standards are  
9 not harmonized, so you can't just assume that because  
10 it passes EP, that it passes USP as well. So you  
11 need to basically take the product or the API and  
12 test it according to USP prior to use to assure that  
13 it meets the USP standards.

14 Q. And how do you do that?

15 A. You send it -- if you don't have a lab, you  
16 send it to a contract lab that has USP testing that's  
17 familiar with the methodology.

18 Q. On page 6 and 7 and 8 and 9 of your  
19 supplemental report, this encompasses Section II of  
20 the supplemental report, it says: Poor recordkeeping  
21 practices.

22 A. Yes.

23 Q. Did you identify any recordkeeping practices,  
24 others that you did not put in here?

25 A. Well, there's a lot of lack of records, yes.

1 So that's the biggest concern. So, I mean, I know  
2 that's a number of concerns that I had.

3 Q. The concerns that you have are in your  
4 supplemental report?

5 A. Yes. And really there are more that would  
6 just expand further on these. It's such a lack of  
7 records, that I really wonder if they are there and  
8 they just have not been disclosed. And my hope and  
9 assumption is that there are, but I don't know.

10 For example, calibration logs for your  
11 balances, those types of things, that's lacking too.  
12 You know, I didn't even go into great detail about  
13 that. My assumption is that, of course, they would  
14 have it, but I don't know.

15 You know, another concern I have is the  
16 quality of the glassware that they use, what class  
17 glass did they use. Again, not mentioned. My  
18 assumption is they use appropriate, but I don't know.

19 MR. SUTHERLAND: Rob, can you pull up, I  
20 guess, what will be Exhibit 9. It will be a  
21 4-21-2017 Nephron Pharmaceuticals Corporation 483.

22 (WHEREUPON, a document was marked as  
23 Exhibit Number 9.)

24 MS. LEONARD: Rob, if you could send that  
25 my way too, I'll send that along to Dr. Almgren.

1 MR. MITCHELL: It is on its way.

2 MS. LEONARD: Great, thanks.

3 MR. SUTHERLAND: Let me know when you  
4 have it, Dr. Almgren.

5 THE WITNESS: Yes.

6 BY MR. SUTHERLAND:

7 Q. While you are waiting on that, so if you can,  
8 again, remind me what a Form 483 is as it relates to  
9 a 503B compounding pharmacy.

10 A. Basically when you have an inspection, you  
11 may be issued a Form 483 if there have been any  
12 issues discovered with the quality of the products.

13 I mean, mostly CGMP-related type of  
14 issues, if you are violating any kind of procedures,  
15 so that may translate to impacting the quality of  
16 your product, obviously. That's what I mean.

17 Q. Are you familiar with Nephron Pharmaceuticals  
18 having been issued Form 483s before?

19 A. We have in the past, yes.

20 Q. And this one in particular which is dated  
21 April 21st of 2017, which would predate your working  
22 there, it contains two observations; is that right?

23 A. Are you asking me?

24 Q. I am asking you, yes.

25 A. I don't have the document. It's really small

1 on my screen. I'm waiting for it to come across, so  
2 I'm sorry.

3 Q. Can you see the screen that's being shared?

4 A. It's very small, I have to really come close  
5 to see it. I have a small laptop. Okay, that's  
6 better.

7 MS. LEONARD: And I just sent it by email  
8 to you, so hopefully it will be there in another  
9 minute or two.

10 THE WITNESS: Thank you.

11 BY MR. SUTHERLAND:

12 Q. So do you see this Exhibit 9, which is -- is  
13 it a Form 483 that was issued to Nephron  
14 Pharmaceuticals Corporation?

15 A. Yes, that's what it appears to be.

16 Q. The outsourcing facility. Is that the  
17 outsourcing facility that you work with?

18 A. Yes.

19 Q. Again, just to be clear, this is dated  
20 April 21st, 2017, which is before you started working  
21 with them.

22 A. Correct.

23 Q. But what is Observation 1 in that 483?

24 A. So the observations, Observation 1 says, the  
25 procedure is designed to prevent microbiological

1 contamination of the drug product.

2 I guess we were not -- did not perform  
3 aseptic process simulation. Oh, we have not  
4 performed aseptic process simulation to validate. I  
5 am not familiar with this one in particular, but I'm  
6 just reading to see what it means.

7 So, obviously, we have not performed the  
8 aseptic process simulations to validate phenylephrine  
9 hydrochloride aseptic sterilization process to  
10 provide evidence and assurance that sterility is  
11 maintained throughout the activities of the process,  
12 okay?

13 Q. Okay.

14 A. Yes.

15 Q. So what does that mean?

16 A. So we have not performed the media fill test  
17 for that particular equipment for that particular  
18 product.

19 Q. And what would happen if you didn't do that,  
20 potentially?

21 A. So you see, I do not know the background, so  
22 I can only guess. But let me just give you a little  
23 bit of a -- little bit of a background with this  
24 particular procedure.

25 So the way that we typically validate the

1 process to demonstrate sterility is we perform media  
2 fill test. So media fill test is basically performed  
3 by using sterile media, and you mimic the procedure  
4 that you are doing.

5 And so basically you run the media fill  
6 through the system that you normally would run a  
7 sterile preparation through. Then you incubate the  
8 media, and if there is any bacterial contamination,  
9 it will flag and show you that that's a quality  
10 issue.

11 So I don't know the details and I would  
12 have to go back and ask what happened, but what my  
13 guess is, that we did not perform media fill for that  
14 specific product.

15 Q. So if you don't do that, what can potentially  
16 happen?

17 A. Well, this is the catch here. A lot of times  
18 we perform the simulation for the equipment, and I  
19 think that's what may have happened. This could  
20 really be a matter of paperwork, because --

21 Q. Wait. Stop for a second. You are not  
22 answering my question.

23 My question is: If you don't do what  
24 they cited in this observation, what can happen?

25 MS. LEONARD: Scott, do you think you

1       could be a little more specific or rephrase the  
2       question? I think that --

3               MR. SUTHERLAND: She wasn't -- sure.

4               THE WITNESS: I'm just confused.

5               MR. SUTHERLAND: Yeah.

6       BY MR. SUTHERLAND:

7       Q.       Well, you weren't having any trouble earlier  
8       talking about all of the potential problems with  
9       doing things with the protocol.

10              What I'm trying to ask you is, does this  
11      inspection reveal a deficiency dealing with aseptic  
12      technique?

13              And I'm asking you what is the potential  
14      problem that could arise if you don't do this?

15      A.       Okay. So there is a two-prong answer.

16      Q.       Okay.

17      A.       So one prong is generally you will need to  
18      perform media fill test to validate your procedure to  
19      be able to demonstrate that you can prepare the  
20      products in a sterile way. So that's the one prong.

21              So, yes, if you do not perform the  
22      procedure, that means that you potentially could be  
23      producing products that may be contaminated. So  
24      that's answer one.

25      Q.       Okay.

1 A. In this case what could have happened, and I  
2 would have to go back and verify --

3 Q. Whoa, whoa, whoa. Ma'am, wait a second. I'm  
4 not asking you what could have happened. That's not  
5 my question. I don't care about what could have  
6 happened.

7 I'm asking you, under this observation,  
8 just like with these other questions I had about the  
9 protocol and what's done, what can happen? And I  
10 think --

11 A. Well --

12 Q. And you are telling me that contamination can  
13 occur; is that right?

14 A. Right. But I need to explain the second part  
15 of this, because again, it will be taken out of  
16 context.

17 What sometimes happens with the  
18 manufacturers is you perform the aseptic process  
19 simulation for a filling line, for manufacturing  
20 line, for one product. And that product you say:  
21 Hey, we performed validation for -- I don't know --  
22 epinephrine.

23 And so then that same line may have been  
24 used for phenylephrine following it, so technically  
25 you did not perform the validation for that process

1 for the phenylephrine, but it has been validated for  
2 other products ran on that same system.

3 And so because of that -- what we do now  
4 is we perform validation that's system related. Back  
5 then, we performed validation that was product  
6 related.

7 So you may have used the production line  
8 for other products and it was validated, producing  
9 perfectly safe products, but if you fail to document  
10 that, then you might have issues like this.

11 Q. You don't know what happened in this regard,  
12 do you?

13 A. Unfortunately, this was before I was there,  
14 so I do not know.

15 Q. What is observation -- what is Observation 2?

16 A. Okay. So lab controls do not include the  
17 establishment of scientifically sound and appropriate  
18 test procedures designed to assure that components  
19 and drug products conform to appropriate standards of  
20 identity, strength, quality and purity.

21 So we have obviously an SOP. Which, by  
22 the way, I have to take pride in this. This SOP has  
23 been updated after I started. I actually had gone to  
24 special training for visual inspection, and I have  
25 revamped our visual inspection training completely.

1 So this is not an issue anymore, I'm sure, but let me  
2 read on.

3 So the current procedure, well, it says,  
4 performing 100 percent visual inspection. Do not  
5 include a representative library. Yes, yes, yes.  
6 Okay. So I understand.

7 So in order to develop properly your  
8 visual inspection quality program, you have to  
9 develop a library of potential defects. And so this  
10 is where we were cited, because we have a very -- at  
11 the time, we had a very small library.

12 So our library was relatively limited  
13 because we were just ramping up our 503B production.  
14 And so at the time I think our library of defects was  
15 much smaller than it is today.

16 So this is something that we were cited  
17 for, and we have corrected, pretty much.

18 Q. What happens if you don't correct it?

19 A. So if you didn't correct it, you know -- and  
20 again keep in mind, so the way that the visual  
21 inspection library is used, so still -- as you see,  
22 we were performing 100 percent visual inspection.

23 That was performed. It's just that there  
24 are reference materials that we used for  
25 identification and for training were not up to date.

1 Q. What happens? What happens?

2 A. What happens what?

3 Q. What happens if you don't fix it?

4 A. Oh, no, we fixed it.

5 Q. I said, what happens -- my question to you  
6 is -- at the time it wasn't fixed. And so my  
7 question to you is: What happened -- what would  
8 happen if you didn't fix it?

9 A. So what would happen is we would still detect  
10 the visual defect; so that part is done. But we  
11 would not be able to identify what was the failure of  
12 the visual inspection defect.

13 Does that make sense? Because your  
14 library does not contain the potential contaminants  
15 that you may have discovered.

16 Q. You didn't have -- Nephron didn't have  
17 controls in place to assure that the components and  
18 its drug product conformed to appropriate standards;  
19 that's what it says, right?

20 MS. LEONARD: Objection to form.

21 THE WITNESS: That's a very general  
22 statement. I would not say that.

23 BY MR. SUTHERLAND:

24 Q. That's what the observation says: Laboratory  
25 controls do not include the establishment of

1 scientifically sound and appropriate test procedures  
2 designed to assure that components and drug products  
3 conform to appropriate standards of identity,  
4 strength, quality and purity.

5 A. Right. So that's a general statement when  
6 the inspector completes the form. I'm pretty sure  
7 that's an autopopulated statement when they perform  
8 inspections of facilities, because do you see how  
9 vague it is? Do you see how kind of general it is?  
10 That is the reason.

11 Yes. I mean, it's generally true, but  
12 it's a very vague statement that's used to kind of  
13 encompass any kind of a quality control issues that  
14 stem in that particular department.

15 Q. What is Observation 3?

16 A. I don't see Observation 3.

17 Q. Do you see it now?

18 A. Yes. The responsibilities and procedures  
19 applicable to the quality control unit are not fully  
20 followed. Pretty straightforward.

21 Q. Tell me about that.

22 A. So that, again, I can only make assumptions  
23 based on what I read, because this was before I was  
24 there.

25 Q. Sure.

1 A. It says: SOP 1501 supplier vendor quality  
2 program is not fully followed in that you have not  
3 established -- whatever it is -- as required by our  
4 SOP with, blank, reviewed.

5 I'm assuming that probably is -- there is  
6 an FDA list of suppliers. There is a list of raw  
7 materials suppliers that you are supposed to have.  
8 And this is Nephron, when we just started being a  
9 503B outsourcing facility.

10 And I am assuming -- again, I wasn't  
11 there -- but I'm assuming at the time when we  
12 started, we just were not aware that that was -- we  
13 were supposed to create a list.

14 At least, that is my assumption. But  
15 that's what it sounds like, that it is a list of  
16 suppliers that we were supposed to be able to  
17 provide.

18 We do have it now. We've had it years.  
19 Since I've been there, we've had it. I'm assuming  
20 perhaps it was the correction for this citation, I  
21 don't know.

22 Q. What would happen if you don't have a list?

23 A. I mean, it may just be more of an  
24 administrative type of problem, because as long as  
25 you are receiving raw materials that are USP grade --

1 and keep in mind, at Nephron we actually have labs  
2 and most of our incoming raw materials we test  
3 according to USP.

4 So we don't even necessarily even rely on  
5 the USP certificates from the manufacturers. We  
6 actually do our own in-house testing to verify that  
7 those procedures are -- you know, those quality  
8 standards are met. So we --

9 Q. The FDA doesn't know that, though, do they?

10 A. Well, when they come -- no, no, they come to  
11 see our facility. They saw our labs.

12 But, you know, if you don't have the list  
13 for their review, then obviously that can become a  
14 citation because, you know, you are to have the list.

15 Like I said, we do have it now. But it  
16 does not necessarily mean -- and I'm pretty sure that  
17 our lab, you know, was testing all of the products,  
18 but I would have to go back to verify.

19 But knowing Nephron, knowing our awesome  
20 management and how well they run the ship and  
21 having -- you know, keep in mind that we have a  
22 manufacturing background. So the owners of Nephron  
23 have been doing this -- they have been in business  
24 for a long time, and so they are very familiar with  
25 the general CGMP.

1                   So I'm surprised that they did not have  
2                   this, but it might be something specific, because we  
3                   have -- now we have a lot more products that we work  
4                   with.

5                   (An off-the-record discussion was held.)

6                   BY MR. SUTHERLAND:

7                   Q.           The reason you have to have a list is why,  
8                   Dr. Almgren?

9                   A.           Well, one of the -- honestly, I don't know  
10                  all of the regulations, so I guess I shouldn't go  
11                  into great detail.

12                  But, in general, traceability, you know,  
13                  make sure that you can verify your sources of APIs.

14                  Q.           Okay. At the time these observations were  
15                  made, you weren't able to do that?

16                  A.           I don't know what happened.

17                  Q.           Observation 4: The container labels of your  
18                  outsourcing facility's drug products are deficient.  
19                  Specifically, the following products did not have  
20                  your firm address and or phone number listed on the  
21                  syringe label.

22                  Is that just a labeling issue?

23                  A.           It certainly sounds like it.

24                  Q.           What is glycopyrrolate?

25                  A.           It's a medication that we use for a variety

1 of uses.

2 Q. Like what?

3 A. I see it commonly in geriatric patients where  
4 they have drooling. Excessive drooling can be one of  
5 them. There are a lot of different uses. It's an  
6 older drug.

7 Q. I think there are five drugs listed.  
8 Neostigmine, what is that?

9 A. Neostigmine, yeah.

10 Q. Neostigmine, what is that?

11 A. If I'm not mistaken, that's used to reverse  
12 anesthesia.

13 Q. And atropine, what's atropine?

14 A. Again, many different uses; older drug. It's  
15 anticholinergic.

16 Q. I'm sorry?

17 A. It's anticholinergic.

18 Q. Give an example.

19 A. It depends on, you know, the atropine can be  
20 used during anesthesia; it can be used for management  
21 of certain types of poisoning.

22 They use it for your eyedrops when they  
23 do your vision test and they put those drops in your  
24 eyes to open your eye, pupils, so they can see the  
25 back of your eye. So --

1 Q. What type of drug is it?

2 A. What do you mean?

3 Q. I'm sorry. What did you say?

4 A. Anticholinergic.

5 Q. Phenylephrine?

6 A. Phenylephrine.

7 Q. What is that?

8 A. Medication used for managing your blood  
9 pressure; people are in shock.

10 Q. And then what's that last one?

11 A. Succinylcholine.

12 Q. Yeah. And what's that for?

13 A. Succinylcholine, let me think. I think that  
14 one is used -- you see, I don't practice in this  
15 area.

16 My area of expertise is really sterile  
17 compounding, and, you know, handling of the drugs,  
18 the regulations that come with that. So, you know,  
19 keep that in mind. I feel like I'm here on a  
20 pharmacy drug quiz.

21 Q. So these container labels -- I mean, what are  
22 these that weren't properly labeled? What are these  
23 drugs being used for? What are they -- why are they  
24 at Nephron? Does that make sense?

25 A. They are shortage drugs, and so that's why we

1 made them at the time. I'm not sure we make any of  
2 them at this point.

3 I know we make -- I think we make  
4 phenylephrine, but I think the neostigmine we maybe  
5 off or on. The atropine I don't think we make right  
6 now. Succinylcholine I'm not sure we make right now.

7 You know, being a 503B outsourcing  
8 pharmacy, you can only make medications that are on  
9 the FDA shortage list, and so we make those.

10 Q. So these were compounded drugs?

11 A. Yes. 503B compounded drugs, yes.

12 Q. And so you get this Form 483, and then what  
13 happens?

14 MS. LEONARD: Objection to form.

15 THE WITNESS: So it depends on your  
16 management. I mean, obviously, you address all of  
17 the issues that you can as soon as possible.

18 MR. SUTHERLAND: Rob, can you put up what  
19 will be Exhibit 10. It should be a Form 483 from  
20 April 20, 2018.

21 MR. MITCHELL: And as always, it's  
22 en route.

23 MS. LEONARD: Okay.

24 (WHEREUPON, a document was marked as  
25 Exhibit Number 10.)

1 BY MR. SUTHERLAND:

2 Q. So just for the record, Dr. Almgren, this  
3 appears to be a Form 483 issued on April 20th of 2018  
4 to Nephron Sterile Compounding Center.

5 Again, is that the compounding facility  
6 that you work for?

7 A. Yes.

8 Q. What's the observation listed in this 483?

9 A. This was the -- I am fully aware of this one,  
10 because even though this happened before I have  
11 really joined Nephron, I believe, but I have heard of  
12 this one.

13 And basically it is a citation that one  
14 of our sterile pharmacy technicians did not have  
15 exactly complete gowning. What happened is, per CGMP  
16 requirements, the gowning for the sterile environment  
17 in a CGMP environment is more stringent.

18 So in a cleanroom in a hospital for 503A,  
19 you actually can have skin exposed. You have to wear  
20 a mask, hair net. I mean, there's a whole special  
21 gowning.

22 But for 503B compounding for outsourcing,  
23 because we have extended beyond use date and because  
24 we have higher sterility dates and requirements, we  
25 basically require -- or, it's required by CGMP that

1 all of the folks that work in a clean environment in  
2 the cleanroom are fully gowned.

3 So in this violation what happened is  
4 there was a young woman, I believe, who worked in the  
5 cleanroom, and she had one of these really big  
6 hairstyles where she had kind of like her hair pulled  
7 up on top of her head.

8 And so she had the gowning on. The  
9 gowning was appropriate, but because of the amount of  
10 hair on her head, when she moved in a certain way, a  
11 portion of her neck was exposed briefly.

12 Q. So what's the concern with the exposure of  
13 her skin in the cleanroom?

14 A. There is potential for contamination. What  
15 we typically do at Nephron -- and I have seen this at  
16 Nephron multiple times -- we actually have air  
17 quality monitoring system in each of our hoods.

18 So when we perform any kind of a sterile  
19 compounding, we still require people to be fully  
20 gowned, but we have a continuous air quality  
21 monitoring system that basically monitors for  
22 presence of any contamination.

23 And so should this small exposure be an  
24 issue, the alarm will go off, and everything that has  
25 been compounded during that time will not be used for

1 patient care.

2 Q. What kind of contamination could occur?

3 A. So it could be particulates. It could be,  
4 you know, bacterial.

5 Q. And what could result from that type of  
6 contamination to the compounds that are being  
7 prepared, the same as what we were talking about  
8 earlier?

9 A. Yes, just what we talked about before. So  
10 like I said, we monitor the environment and, you  
11 know, if alarms go off -- like I said, we require  
12 full gowning.

13 So, of course, that was a violation  
14 because there was a brief period, a very short  
15 exposure where a person's neck was exposed, as it  
16 states in the statement.

17 Anyway, the air monitoring will alert you  
18 if the particulate matter had entered the sterile  
19 area, and in that case we will stop any production  
20 and everything is discarded.

21 MR. SUTHERLAND: Rob, can you put up what  
22 will be Exhibit 11, and send that to Ms. Leonard and  
23 Dr. Almgren.

24 ///

25 ///

1 (WHEREUPON, a document was marked as  
2 Exhibit Number 11.)

3 (An off-the-record discussion was held.)

4 BY MR. SUTHERLAND:

5 Q. Dr. Almgren, for the record, this appears to  
6 be a Form 483 issued to the Nephron Sterile  
7 Compounding Center on November 15th of 2019.

8 A. Uh-huh.

9 Q. Are you familiar with this inspection?

10 A. I do remember an inspection vaguely, but I do  
11 remember it.

12 Q. Okay. Can you tell me what -- I'll wait  
13 until you have it so you can read it.

14 A. Yes.

15 Q. Yeah. Dr. Almgren, who gets presented with  
16 these Form 483 by the investigators when they --

17 A. It is our CEO, Lou Kennedy.

18 Q. Okay. And are you part of the review process  
19 in your capacity when you-all receive one of these  
20 when you are there?

21 A. Not necessarily, because some of these are  
22 outside of the scope of my practice, so not  
23 necessarily.

24 Q. What do you mean by outside the scope of your  
25 practice?

1 A. So, you know, if it has something to do with  
2 things that I really -- you know, like engineering  
3 controls, for example. That will be more of an  
4 engineering type of response. That would not be  
5 something that I would be able to address.

6 Okay. I received the document, I'll look  
7 at it.

8 Q. Observation 1: Test procedures relative to  
9 appropriate lab testing for sterility are not written  
10 and followed.

11 And then it gives: Specifically the  
12 firm's written procedures for conducting rapid  
13 sterility testing are deficient in that -- and it  
14 gives three -- it actually gives five examples.

15 If you can look at those, and if you are  
16 able to comment on them, I'd like what your --

17 A. Fortunately, I'm looking at the microbiology  
18 report, the rapid sterility. I really don't know  
19 what the "background too high," what that refers to,  
20 so that makes it difficult to make any educated  
21 statements. I would have to go back and ask what  
22 that was specifically --

23 Q. I understand. Number 4: Firm does not have  
24 procedures requiring eye exams for individuals that  
25 conduct review of rapid sterility test sample

1 results.

2 A. Again, this is more of an HR issue. I'm  
3 assuming that they did not screen -- I don't know.  
4 The rapid sterility testing, this refers to  
5 microbiology testing for the sterile preparations.

6 Q. Procedure --

7 A. It's just a part of it. I'm sorry, that's  
8 all.

9 Q. All right. Procedures did not require  
10 observance of actual positive microbial events by an  
11 analyst prior to performance of sterility testing  
12 conducted for commercial products. It was observed  
13 that an individual was allowed to conduct an  
14 inspection of rapid sterility samples, including  
15 prior to completion of activities, and demonstrate  
16 they have seen and can identify what a positive  
17 microbial event looks like. For example, during the  
18 period from October 3, '19 to October 29, '19, a lab  
19 associate was allowed to conduct finished product  
20 rapid sterility testing prior to the associate  
21 participating in a method validation on October 29,  
22 2019. Where, according to firm management, they  
23 would have been -- they would have seen and  
24 identified a positive microbial event example for the  
25 first time at the first. During this time the

1 associate conducted tests from multiple lots of  
2 product, including but not limited to rapid sterility  
3 sample sets.

4 Are you familiar with this particular  
5 observation in this --

6 A. No, I am not. You know, microbiology lab is  
7 in management. You know, keep in mind, the company  
8 has 2,500 employees, if not more by now, and so I  
9 don't keep up with all of these. I honestly am not  
10 familiar with what happened there either.

11 Q. Observation 2: Procedures designed to  
12 prevent microbiological contamination of drug  
13 products purporting to be sterile are not followed.

14 Is this something that you are familiar  
15 with?

16 A. I don't know. Let me read it all. I'm not  
17 familiar with the second observation. Let me look at  
18 this.

19 See, this is a great example. I love  
20 that you have pulled up this, because this really  
21 shows how the aseptic technique matters, and how such  
22 a small issue, what may seem to you as a layperson,  
23 how serious of a violation it is.

24 So I'm really glad that you are bringing  
25 this up. Thank you for bringing this up, because,

1 again, it illustrates the importance of the aseptic  
2 technique and how -- I mean, here we are talking  
3 about the way that the operator was handling, you  
4 know, how the caps were handled and how the door was  
5 open.

6 So I hope that this, if anything else,  
7 also illustrates the importance of aseptic technique  
8 and how much of a concern it is to make sure that the  
9 products are -- you know, it maintains sterility.

10 So, again, I'm reading this with you. I  
11 do not remember this incident in great detail, but I  
12 deal with sterile techniques. I think we did  
13 training afterwards. Like I said, I don't remember.

14 I probably, at the time I was there -- so  
15 at the time I'm pretty sure, you know, I dealt with  
16 this as in I have heard about it. But it's been a  
17 while, so I don't remember all of the details.

18 But as I'm reading it, I'm thinking,  
19 well, it kind of rings a bell. And I think we did  
20 some additional training to address this.

21 Q. Observation 3: Aseptic processing areas are  
22 deficient regarding the system for monitoring  
23 environmental conditions.

24 Will you look at that and tell me if you  
25 are familiar with this one?

1 A. Yes, this is an interesting one. I do  
2 remember this one. They are quickly tapping their  
3 fingertips on each media plate.

4 Yes, so this refers to how the -- how the  
5 personnel monitoring is done. And this is very  
6 person specific. So, you know, when FDA comes -- and  
7 this is something you have to keep in mind as well.

8 You know, the FDA comes and does  
9 inspection, it's a point in time. So they come in,  
10 and whatever they observe at a time is what you learn  
11 from these inspection forms, you know. So you have  
12 to look beyond just those and look at the quality  
13 reports and standards that they follow in the big  
14 scale of things.

15 But in this one it's obviously the  
16 technique, the proper technique for the personnel  
17 monitoring was not exactly as it should be.

18 Q. Go back up to Observation 2, what on the  
19 aseptic technique issue that you are talking about --  
20 if the person that was observed doing this that  
21 resulted in the observation, how do you -- I guess  
22 what I'm trying to figure out is, they were preparing  
23 a product, right?

24 A. Yes.

25 Q. So was that product discarded?

1 A. So we perform extensive quality control  
2 after -- you know, after every batch is made, every  
3 product that's made, we perform sterility studies.  
4 We perform assay, endotoxin, all that's required per  
5 USP.

6 So I cannot honestly tell you whether  
7 these observations had resulted in those particular  
8 products to be discarded, because I honestly do not  
9 know. I --

10 Q. They might not have been -- they might not  
11 have needed to be discarded, right?

12 A. Well, it depends. The quality assurance or  
13 quality control testing is performed when these  
14 products are finished.

15 Q. Right.

16 A. If they meet the quality standards, they  
17 potentially could be used, but, again, it depends.  
18 But, you know, this is a prime example where you see  
19 the operator in this Observation part 2, when you  
20 read on the top of the page -- what is this, page 3,  
21 I guess, where it talks about the -- yes, yes, right  
22 up there.

23 So it says, you know, the violation was  
24 that the person just moved their arm over the cap  
25 scoops containing caps. And so they blocked the

1 first air and there's a potential for, you know, just  
2 a minor, you know, contamination just from movement  
3 of the air.

4 So it just tells you how important  
5 aseptic technique is and how important it is to not  
6 contaminate, for example, caps. Which a cap is,  
7 obviously, concerned critical site.

8 Q. Do you know whether this resulted in having  
9 to not use product?

10 A. I do not know.

11 Q. Is it possible that it didn't?

12 MS. LEONARD: Objection.

13 THE WITNESS: I don't know. I would have  
14 to see the quality. I could see what was done.

15 BY MR. SUTHERLAND:

16 Q. Observation 4: Written procedures for  
17 sampling and testing plans are not followed for each  
18 drug product.

19 Are you familiar with this?

20 A. Let me look. Yes. I do remember this  
21 because we had a training afterwards. And,  
22 basically, this just shows you, again, the importance  
23 of visual inspection and how you have to have the  
24 proper technique.

25 So what's happening here was the

1 technician instead of slowly inverting, or, you know,  
2 in a normal controlled motion observing the syringe,  
3 you know, to flip it over to make sure that you see  
4 any contaminants moving within the syringe, they  
5 inverted it quickly and, you know, did kind of a --  
6 they didn't do proper technique, and so we were cited  
7 on that.

8 So we were cited in that our visual  
9 inspectors did not -- it was one inspector, and I  
10 actually talked with this person afterwards. And  
11 they said they just got a little nervous when FDA was  
12 standing and watching them.

13 But, you know, FDA doesn't care, you need  
14 to show your proper technique. So it is what it is,  
15 we did the proper training afterwards. And it is --  
16 the SOP 4301 does talk about how you are supposed to  
17 perform that motion.

18 Q. Observation 5: Aseptic processing areas are  
19 deficient in the floors and walls are not smooth  
20 and/or hard surfaces that are easily cleanable.

21 Are you familiar with that?

22 A. So that's more of an engineering department  
23 than my department, but our floors and our walls are  
24 sealed. So there's a proper seal that we have on all  
25 of them to, you know, have the nonshedding surface to

1 maintain the room, you know, to prevent any pieces  
2 come in the walls and contaminating.

3 But in terms of the smoothness, again,  
4 outside of my expertise in terms of how that was  
5 addressed or anything like that.

6 Q. Observation 6: Aseptic processing areas are  
7 deficient regarding the system for cleaning and  
8 disinfecting the room and equipment to produce  
9 aseptic conditions.

10 Are you familiar with this observation?

11 A. I'm sorry. I'm reading, just so you know --

12 Q. Sure.

13 A. -- the entire paragraph.

14 Yeah, this is more of an environmental  
15 control, obviously, issue.

16 Q. Relating to?

17 A. Cleaning procedure.

18 Q. So, basically, there was a cleaning procedure  
19 that wasn't being followed?

20 A. That's what it sounds like, yes.

21 Q. Observation 7: Established test procedures  
22 are not documented at the time of performance.

23 Are you familiar with this?

24 A. So that is really just, I think, again, a  
25 more specific issue. It appears like it is relating

1 to employees, really, more not when they -- you are  
2 supposed to -- when the task is performed, you need  
3 to record it right away.

4 And what sometimes happen is they finish  
5 the task and then they go and record it. And so if  
6 you are recording it not at a time when it happened,  
7 it is not appropriate.

8 Q. Observation 8: Appropriate controls are not  
9 exercised over computers or related systems to assure  
10 that changes in master production and control records  
11 or other records are instituted only by authorized  
12 personnel.

13 Are you familiar with this?

14 A. Outside of my expertise. That's an IT and  
15 technology department. I have no control over that.

16 Q. Does this relate to access, who has access to  
17 the information?

18 A. We have very limited access, so I do not know  
19 how that happened. I'm not really sure what that was  
20 in regards to. It sounds almost like -- let me read  
21 this again.

22 It sounds like there's some backup data  
23 missing. Again, I don't know.

24 Q. Okay. Observation 9: There's a failure to  
25 thoroughly review any unexplained discrepancy whether

1 or not the batch has been already distributed.  
2 Specifically, the firm does not conduct  
3 investigations when finished product rapid sterility  
4 samples are deemed background too high. Samples were  
5 deemed background too high approximately 23 times in  
6 the last 90 days, with no investigations performed.  
7 Source nor cause of the high event counts have been  
8 identified. The product is without identification of  
9 the cause, nor examination to identify the events.

10 Are you familiar with this?

11 A. I'm not familiar with this exact citation,  
12 it's exactly -- I think it was already kind of  
13 mentioned up earlier as one of the -- part of another  
14 citation up here about the background too high,  
15 and --

16 Q. What does that mean?

17 A. So that's what I'm trying to decipher, what  
18 exactly does that mean, because that does not refer  
19 to the product failure.

20 The products, you know, we perform  
21 microbiological testing of all of our products, and,  
22 of course, if those were to fail, you are not going  
23 to release those.

24 So I'm not sure what the "background too  
25 high" is. I don't know whether that relates to

1 technology or the rapid sterility testing; I'd have  
2 to go back and ask.

3 Again, microbiology, this is a  
4 microbiology lab that had undergone some major  
5 changes after this inspection.

6 MR. SUTHERLAND: Lynne, can we take about  
7 a 10-minute break?

8 MS. LEONARD: Yeah, that's fine. Do you  
9 think you have much more to go?

10 MR. SUTHERLAND: I'm getting pretty  
11 close.

12 (An off-the-record discussion was held.)

13 BY MR. SUTHERLAND:

14 Q. Dr. Almgren, I think I'm almost finished.  
15 Let me ask you this.

16 Have you -- as part of your work in this  
17 case, were you asked to attempt to locate any source  
18 of pentobarbital or any other lethal injection  
19 chemicals on behalf of the plaintiff?

20 A. What? No. To locate pentobarbital? No.

21 Q. You weren't asked to help locate a source for  
22 pentobarbital?

23 A. No.

24 Q. Or any other lethal injection chemical?

25 A. No.

1 Q. Or any other chemical?

2 A. No. Obtain, you mean like -- no.

3 Q. Well, let me clarify.

4 Were you asked to attempt to locate  
5 pentobarbital or any other chemical that Tennessee  
6 might be able to use as an alternative to its current  
7 protocol?

8 MS. LEONARD: Objection. This is getting  
9 into privileged material.

10 BY MR. SUTHERLAND:

11 Q. Okay. Dr. Almgren, are you familiar with any  
12 source that would provide pentobarbital to the  
13 Tennessee Department of Corrections for lethal  
14 injection executions?

15 A. I am not.

16 Q. Okay. Are you familiar with any source that  
17 would provide any other lethal injection chemicals or  
18 other chemicals to the Tennessee Department of  
19 Corrections for use in judicial executions?

20 A. I don't know of any. I don't know what you  
21 mean by that. No. I did not -- I'm not sure what  
22 you are asking.

23 Q. Okay. Have you searched for pentobarbital or  
24 sources of pentobarbital that the Tennessee  
25 Department of Corrections could use in lethal

1 injection executions?

2 A. No.

3 Q. Okay. Or any other chemicals?

4 A. No.

5 Q. You have not. Okay.

6 How did you get involved in the -- it  
7 looks to me that your first -- was your first  
8 involvement in the lethal injection issue in the  
9 cases we talked about earlier, like in '19, 2019,  
10 '18, '19?

11 A. Yes.

12 Q. How did you get involved in this area?

13 A. I was asked to provide expert testimony or  
14 expert, I guess, report.

15 Q. And how did you get identified as -- did  
16 somebody cold call you and say: We are looking for  
17 an expert, just out of the blue?

18 A. Yes.

19 Q. And when was the first time that you received  
20 a call like that?

21 A. So I was an expert witness for the Swearingen  
22 case in Texas.

23 Q. So the lawyers for Swearingen just called you  
24 out of the blue?

25 A. It was not -- I believe there was some other

1 office person or some -- I think it was -- I'm trying  
2 to remember what was the -- I think it was  
3 actually -- let me remember before I say anything.  
4 Let me try to remember.

5 I think it was an organization called  
6 Reprieve that had reached out to me.

7 Q. And what is that organization?

8 A. I believe that they are opposing death  
9 penalty, and they basically, I think, support maybe  
10 whenever there are cases like this.

11 Q. And so you just got a call out of the blue  
12 from this organization or somebody from the  
13 organization?

14 A. Yes.

15 Q. Do you know how they got your contact  
16 information?

17 A. I can only assume -- I teach a lot of aseptic  
18 technique and sterile compounding. And their  
19 interest was to get my expert opinion on aseptic  
20 technique, whether the aseptic technique that is used  
21 for preparation of lethal injections is appropriate.

22 And so they provided me some, you know,  
23 materials for review and I provided my expert  
24 opinion, and they felt that it was sufficient.

25 Q. So the first contact you had was from

1       somebody that was with this organization?

2       A.       Yes.

3       Q.       Okay. And was that different than the  
4       attorneys for Mr. Swearingen?

5       A.       I honestly am not sure whether they work  
6       together or --

7       Q.       Was it an attorney that contacted you first?

8       A.       I'm not sure if that was an attorney.  
9       Honestly, I just don't remember; it's been a while.

10      Q.       But you think the organization was called  
11      Reprieve?

12      A.       Yes.

13      Q.       Do you have any personal views on capital  
14      punishment?

15      A.       I do now, doing more research in this area.

16      Q.       What are your personal views?

17      A.       I mean, I honestly don't think it's morally  
18      right to kill a person. I don't think you can ever  
19      justify.

20      Q.       And tell me about that a little bit. Why do  
21      you feel that way?

22      A.       I just think that there is never a right  
23      reason to kill a person, and so I think it's just  
24      wrong.

25                   And seeing this, you know, how in this --

1 a lot of people basically may end up on death row,  
2 and there are even potentially some that may be  
3 innocent, it really is not a good thing.

4 Q. And how long have you felt this way?

5 A. I mean, I never supported the death penalty,  
6 but I never really thought about it in great length  
7 until I really started looking more into it.

8 But I always felt that it is just  
9 morally -- it's not -- I personally believe it is  
10 wrong to put a person to death.

11 Q. And you would say that whether it was lethal  
12 injection or any other method?

13 A. Yes.

14 Q. And is that something that you have arrived  
15 at working on these cases?

16 A. As I said, I always felt that it was not the  
17 right thing to do, but working on these cases, I  
18 really solidified my view.

19 Q. And what was it --

20 A. I feel that medications should not be used --  
21 if we are talking about lethal injection, the  
22 medications are meant for people to get well. They  
23 are meant to heal people. They are not meant to  
24 harm, and definitely not meant to kill a person.

25 Q. So you think lethal injection itself

1 shouldn't be allowed because of that reason?

2 A. Right.

3 Q. Are those opinions you have about capital  
4 punishment, are those opinions that you have shared  
5 with other people?

6 A. Perhaps at times, yes.

7 Q. Like who have you shared those opinions with?

8 A. I mean, my husband.

9 Q. Colleagues within your profession?

10 A. Perhaps some of them, if the conversation  
11 came up, but I would not necessarily bring up the  
12 conversation by itself. But if it did happen, I  
13 would not be ashamed of expressing my personal view.

14 Q. Have you talked about your views about lethal  
15 injection with colleagues in the pharmacy within your  
16 profession as a pharmacist?

17 A. In a pharmacy where I -- any pharmacy  
18 colleagues?

19 Q. My question is, colleagues at the  
20 university -- at the university that you work with,  
21 have you discussed your views with them in  
22 conversations?

23 A. I don't think we had these types of  
24 conversations, so I don't think so. At least, I'll  
25 put it this way, I do not recall any specific

1 conversations that we would have about this.

2 I don't remember. If I did, it must have  
3 been a while back, but I don't remember.

4 MR. SUTHERLAND: Dr. Almgren, I think  
5 that's all of the questions I have for you today. I  
6 appreciate your time.

7 Lynne, thank you.

8 THE REPORTER: Did you need this typed  
9 up?

10 MS. LEONARD: Yes. If we could have a  
11 copy of the transcript, that would be great. Thank  
12 you. Send it to the Federal Community Defender  
13 Office.

14 THE REPORTER: Scott, did you want this  
15 typed up?

16 MR. SUTHERLAND: Yes, the original.

17 FURTHER DEPONENT SAITH NOT

18 (Proceedings concluded at 4:18 p.m.)  
19  
20  
21  
22  
23  
24  
25

REPORTER'S CERTIFICATE

STATE OF TENNESSEE

COUNTY OF DAVIDSON

I, SANDRA ANDRYS, LCR, RPR, RMR, with offices in Nashville, Tennessee, hereby certify that I reported the foregoing videoconference deposition of DR. MICHAELA ALMGREN by machine shorthand to the best of my skills and abilities, and thereafter the same was reduced to typewritten form by me.

I further certify that I am not related to any of the parties named herein, nor their counsel, and have no interest, financial or otherwise, in the outcome of the proceedings.

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